

US3312224 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:03:13

All time stamps listed in this document are displayed in GMT

US3312224

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

Participant ID

US3312224

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

US3312224

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Date of Birth (MMM yyyy)	(b) (6) 1936
Age	84
Age Units	YEARS
Age (Derived)	84
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

Condition	CORONARY ARTERY BYPASS GRAFTING X3 VESSELS
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

US3312224

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

Condition	HYPOTHYROIDISM
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)	

US3312224

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

Condition	MILD CONSTIPATION
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 (7)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1950
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 1950
Start Year (derived)	1950
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3312224

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1950
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 1950
Start Year (derived)	1950
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:55 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 08:55
Height (<i>xxx.x</i>)	72 in
Weight (<i>xxx.x</i>)	170 lb
BMI (<i>xxx.x</i>)	23.10435 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input checked="" 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) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:12:54

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:12:54

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 187622

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

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) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

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)	24 AUG 2020
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 08:55
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

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)	24 AUG 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 10:35
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 10:02 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 10:02

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 AUG 2020
Collection time (00:00-23:59)	09:27 (24 HR)
Collection date and time (derived)	24 AUG 2020 09:27

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:18	24 AUG 2020 09:18
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

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 17:03:13

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

98.0 °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

24 AUG 2020 10:48

PC Open Date & Time

24 AUG 2020 10:22

PC Close Date & Time

24 AUG 2020 12:52

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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 97.0 °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	24 AUG 2020 19:32
PC Open Date & Time	24 AUG 2020 13:47
PC Close Date & Time	25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.9 °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

25 AUG 2020 17:04

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 16:14

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

93.0 °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

27 AUG 2020 16:46

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

28 AUG 2020 16:30

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 16:02

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

98.0 °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

30 AUG 2020 15:59

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

24 AUG 2020 10:50

PC Open Date & Time

24 AUG 2020 10:22

PC Close Date & Time

24 AUG 2020 12:52

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

24 AUG 2020 19:32

PC Open Date & Time

24 AUG 2020 13:47

PC Close Date & Time

25 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

25 AUG 2020 17:05

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

26 AUG 2020 16:15

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

27 AUG 2020 16:46

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

28 AUG 2020 16:30

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

29 AUG 2020 16:03

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

30 AUG 2020 16:00

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 10:51
PC Open Date & Time	24 AUG 2020 10:22
PC Close Date & Time	24 AUG 2020 12:52

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 19:33
PC Open Date & Time	24 AUG 2020 13:47
PC Close Date & Time	25 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 17:06
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

56 of 2580

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 16:15
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

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 ☒

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 16:47
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

60 of 2580

EAB) (1725)

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 16:31
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

62 of 2580

EAB) (1725)

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 16:03
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

64 of 2580

EAB) (1725)

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 16:00
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3312224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

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)	21 SEP 2020
Time of assessment (00:00-23:59)	08:49 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 08:49
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

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)	21 SEP 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:36
Temperature (xxx.x)	97.6 F
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3312224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 10:05

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

What was the frequency of the study treatment dosing? ONCE

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

US3312224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	09:27 (24 HR)
Collection date and time (derived)	21 SEP 2020 09:27

US3312224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:12	21 SEP 2020 09:12
Nasopharyngeal Swab 2	No		

US3312224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 10:45

PC Open Date & Time

21 SEP 2020 10:25

PC Close Date & Time

21 SEP 2020 12:55

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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 97.7 °F

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

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

PC Time Stamp	21 SEP 2020 16:00
PC Open Date & Time	21 SEP 2020 13:50
PC Close Date & Time	22 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

98.3 °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

22 SEP 2020 16:12

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

98.9 °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

23 SEP 2020 16:15

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

24 SEP 2020 16:11

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 15:57

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 14:37

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

27 SEP 2020 14:37

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

21 SEP 2020 10:46

PC Open Date & Time

21 SEP 2020 10:25

PC Close Date & Time

21 SEP 2020 12:55

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

5

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

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

Yes ☒

No ☐

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

5

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

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

21 SEP 2020 16:04

PC Open Date & Time

21 SEP 2020 13:50

PC Close Date & Time

22 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

10

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 16:13

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

10

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 16:15

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

10

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 16:11

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

9

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 15:58

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

7

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 14:38

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

7

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 14:37

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 10:47
PC Open Date & Time	21 SEP 2020 10:25
PC Close Date & Time	21 SEP 2020 12:55

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 16:05
PC Open Date & Time	21 SEP 2020 13:50
PC Close Date & Time	22 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 16:13
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

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)

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 16:12
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

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 ☒

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 15:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 14:38
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 14:38
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

7

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

PC Time Stamp 28 SEP 2020 16:05

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 9

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

7

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

PC Time Stamp 29 SEP 2020 15:48

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 10

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

7

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

PC Time Stamp

30 SEP 2020 16:11

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(11)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 11

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

6

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

PC Time Stamp 01 OCT 2020 16:15

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(12)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 12

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

6

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

PC Time Stamp 02 OCT 2020 15:48

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(13)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 13

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

6

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

PC Time Stamp 03 OCT 2020 16:24

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(14)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 14

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

5

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

PC Time Stamp 04 OCT 2020 14:30

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(15)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 15

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

5

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

PC Time Stamp 05 OCT 2020 16:02

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(16)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 16

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

5

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

PC Time Stamp 06 OCT 2020 15:43

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(17)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 17

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

4

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

PC Time Stamp 07 OCT 2020 14:52

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(18)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 18

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

4

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

PC Time Stamp 08 OCT 2020 15:38

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(19)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 19

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

4

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

PC Time Stamp 09 OCT 2020 15:23

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(20)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 20

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

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

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(21)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 21

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

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

PC Time Stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 SEP 2020 16:06
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 15:48
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 16:12
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 OCT 2020 16:15
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 15:49
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 OCT 2020 16:24
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 OCT 2020 14:30
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 16:02
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 15:43
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 OCT 2020 14:52
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	08 OCT 2020 15:39
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 15:23
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:53

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	08:32 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 08:32
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 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)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3312224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

09:21 (24 HR)

Collection date and time (derived)

19 OCT 2020 09:21

US3312224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:12:54

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	26 OCT 2020 16:31:59
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

02 NOV 2020 15:31:08

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 16:17:12
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 17:53:09
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 15:31:22
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 16:23:50
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 131

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

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 11:40:02
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

20 JAN 2021 14:23:25

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

28 JAN 2021 11:54:31

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

12 FEB 2021 08:31:13

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	04 MAR 2021 12:00:13
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 <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 MAR 2021 17:15:08
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 <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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

25 MAR 2021 17:37:21

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

02 APR 2021 15:46:51

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

08 APR 2021 16:30:14

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 19:05:16
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

22 APR 2021 15:11:26

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 17:30:36

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 292

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2021 00:01
Patient Cloud Close Date & Time	11 JUL 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 327

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

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

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

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

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

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

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

Patient Cloud Open Date & Time	25 AUG 2021 00:01
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Patient Cloud Close Date & Time	29 AUG 2021 23:59
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US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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°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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

Patient Cloud Open Date & Time	06 OCT 2021 00:01
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Patient Cloud Close Date & Time	10 OCT 2021 23:59
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US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 <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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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°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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 JAN 2022 00:01
Patient Cloud Close Date & Time	23 JAN 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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="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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	28 SEP 2022 00:01
Patient Cloud Close Date & Time	02 OCT 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	26 OCT 2022 00:01
Patient Cloud Close Date & Time	30 OCT 2022 23:59

US3312224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:03:13

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		04 MAR 2021 12:00:33

US3312224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:26:00

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:00

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:26:00

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:00

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:26:00

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:00

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:26:00

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:00

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 19:58:21

Generated On: 09 Jun 2021 17:03:13

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

Visit date (dd MMM yyyy)	01 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Apr 2021 19:58:21

Generated On: 09 Jun 2021 17:03:13

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) _____

US3312224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 19:58:21

Generated On: 09 Jun 2021 17:03:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 APR 2021

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

US3312224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Apr 2021 19:58:21

Generated On: 09 Jun 2021 17:03:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	01 APR 2021
Collection time (<i>00:00-23:59</i>)	12:14 (24 HR)
Collection date and time (derived)	01 APR 2021 12:14

US3312224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:58:21

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312224

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:03:13

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"/>

US3312224

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:03:13

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3312224

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:25:59

Generated On: 09 Jun 2021 17:03:13

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

Visit date (dd MMM yyyy)	21 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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US3312224

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:25:59

Generated On: 09 Jun 2021 17:03:13

Date of updated informed consent (<i>dd MMM yyyy</i>)	21 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	21 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3312224

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 21:25:59

Generated On: 09 Jun 2021 17:03:13

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

US3312224

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:25:59

Generated On: 09 Jun 2021 17:03:13

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 JAN 2021
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 12:20
Temperature (xxx.x)	98.0 F
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)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3312224

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:25:59

Generated On: 09 Jun 2021 17:03:13

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 JAN 2021
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 13:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3312224

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:25:59

Generated On: 09 Jun 2021 17:03:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 JAN 2021

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

US3312224

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:25:59

Generated On: 09 Jun 2021 17:03:13

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 21 JAN 2021

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

Treatment Date and Time (derived) 21 JAN 2021 13:24

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

US3312224

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:25:59

Generated On: 09 Jun 2021 17:03:13

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

Collection date (dd MMM yyyy)	21 JAN 2021
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Collection time (00:00-23:59)	12:11 (24 HR)
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Collection date and time (derived)	21 JAN 2021 12:11
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US3312224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:03:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	12:10
Collection Date and Time (derived)	21 JAN 2021 12:10

US3312224

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:25:59

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:01

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:03:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:03:13

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 FEB 2021
Time of assessment (00:00-23:59)	10:14 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 10:14
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:03:13

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 FEB 2021
Time of assessment (00:00-23:59)	12:14 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 12:14
Temperature (xxx.x)	98.3 F
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3312224

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:03:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 FEB 2021

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

US3312224

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:03:13

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 18 FEB 2021

What was the treatment time? (00:00-23:59) 11:43 (24 HR)

Treatment Date and Time (derived) 18 FEB 2021 11:43

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

US3312224

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:26:00

Generated On: 09 Jun 2021 17:03:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:26:00

Generated On: 09 Jun 2021 17:03:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312224

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 19:58:21

Generated On: 09 Jun 2021 17:03:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Apr 2021 19:58:21

Generated On: 09 Jun 2021 17:03:13

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) _____

US3312224

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 19:58:21

Generated On: 09 Jun 2021 17:03:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 APR 2021

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

US3312224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Apr 2021 19:58:21

Generated On: 09 Jun 2021 17:03:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 APR 2021
Collection time (00:00-23:59)	12:14 (24 HR)
Collection date and time (derived)	01 APR 2021 12:14

US3312224

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:52:06

Generated On: 09 Jun 2021 17:03:13

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 17:27:45

Generated On: 09 Jun 2021 17:03:13

AEID

Adverse event

ECCHYMOSIS AT INJECTION
SITE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 SEP 2020

Start time (00:00-23:59)

10:08 (24 HR)

AE start date and time (derived)

21 SEP 2020 10:08

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 17:27:45

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 17:27:45

Generated On: 09 Jun 2021 17:03:13

AEID	USA-US300-2021-MRNA-1273-P30 1000018
Adverse event	INTRACRANIAL HEMMORRHAGE
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)	19 FEB 2021
Start time (00:00-23:59)	01:00 (24 HR)
AE start date and time (derived)	19 FEB 2021 01:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 MAR 2021
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)	19 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	25 FEB 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 17:27:45

Generated On: 09 Jun 2021 17:03:13

Number of Days in ICU	4
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 17:27:45

Generated On: 09 Jun 2021 17:03:13

84YO HISTORY OF HTN, CAD, HYPOTHYROIDISM AND CONSTIPATION RECEIVED 1ST VACCINATION OL V1 21JAN2021 AND DEVELOPED MODERATE ABDOMINAL PAIN WITH MINIMAL IMPACT ON ADLS WHICH RESOLVED 10FEB2021 AND BRUISING AT INJECTION SITE. AT OL V2: ABD PAIN AND BRUISING WERE DISCUSSED WITH PT AND THOUGHT TO BE DUE TO CONSTIPATION AND ASA USE RESPECTIVELY, AS BOTH CONSTIPATION AND EASY BRUISING (STATED BY PT TO BE DUE TO ASA AND PREVIOUSLY DISCUSSED WITH PCP AND CARDIOLOGIST) HAVE BEEN PRESENT CHRONICALLY. (ABD PAIN POST NOT MAAE, SO NOT RECORDED IN EDC) ON 02/19/21 SUBJECT FELL AND HIT HIS HEAD, TAKEN TO ER. SUFFERED SUBARACHNOID AND SUBDURAL INTRACRANIAL BLEEDS AND FOUND TO HAVE PLATELETS OF 37. WAS INITIALLY HYPOTENSIVE REQUIRING PRESSOR SUPPORT BUT AT TIME OF CALL-NO LONGER NECESSARY AND SUBJECT WAS STABLE. WILL PROCURE

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Folder: Adverse Events

Form: Adverse Events (2)

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MEDICAL RECORDS.
23MAR2021: SEE FOLLOW UP
NARRATIVE SENT TO SAFETY
TEAM DUE TO NOT ENOUGH
CHARACTERS ALLOWED.
02APR21: SEE F/U NARRATIVE
SENT TO SAFETY TEAM DUE TO
NOT ENOUGH CHARACTERS
ALLOWED.

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)	1

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Folder: Adverse Events

Form: Adverse Events (3)

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AEID	USA-US300-2021-MRNA-1273-P30 1000018
Adverse event	MYELOYDYSPLASTIC SYNDROME
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)	19 FEB 2021
Start time (00:00-23:59)	01:00 (24 HR)
AE start date and time (derived)	19 FEB 2021 01:00
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)	19 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	24 FEB 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Number of Days in ICU	4
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 17:27:45

Generated On: 09 Jun 2021 17:03:13

84YO HISTORY OF HTN, CAD, HYPOTHYROIDISM AND CONSTIPATION RECEIVED 1ST VACCINATION OL V1 21JAN2021 AND DEVELOPED MODERATE ABDOMINAL PAIN WITH MINIMAL IMPACT ON ADLS WHICH RESOLVED 10FEB2021 AND BRUISING AT INJECTION SITE. AT OL V2: ABD PAIN AND BRUISING WERE DISCUSSED WITH PT AND THOUGH TO BE DUE TO CONSTIPATION AND ASA USE RESPECTIVELY, AS BOTH CONSTIPATION AND EASY BRUISING (STATED BY PT TO BE DUE TO ASA AND PREVIOUSLY DISCUSSED WITH PCP AND CARDIOLOGIST) HAVE BEEN PRESENT CHRONICALLY. (ABD PAIN POST NOT MAAE, SO NOT RECORDED IN EDC) ON 02/19/21 SUBJECT FELL AND HIT HIS HEAD, TAKEN TO ER. SUFFERED SUBARACHNOID AND SUBDURAL INTRACRANIAL BLEEDS AND FOUND TO HAVE PLATELETS OF 37. WAS INITIALLY HYPOTENSIVE REQUIRING PRESSOR SUPPORT BUT AT TIME OF CALL-NO LONGER NECESSARY AND SUBJECT WAS STABLE. WILL PROCURE

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 17:27:45

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MEDICAL RECORDS.3/23/21: SEE
UPDATED SAE NARRATIVE
SENT TO SAFETY TEAM DUE TO
NOT ENOUGH CHARACTERS
ALLOWED. 02APR21:SEE
UPDATED SAE NARRATIVE
SENT TO SAFETY TEAM DUE TO
NOT ENOUGH CHARACTERS
ALLOWED.

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)	1

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 17:27:45

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AEID	
Adverse event	HEAD LACERATION
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)	19 FEB 2021
Start time (00:00-23:59)	01:00 (24 HR)
AE start date and time (derived)	19 FEB 2021 01:00
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 type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Form: Adverse Events (4)

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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	False
Concomitant Medication	False
Concomitant Procedure	True
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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 17:27:45

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AEID

Adverse event

SYNCPAL EPISODE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 FEB 2021

Start time (00:00-23:59)

01:00 (24 HR)

AE start date and time (derived)

19 FEB 2021 01:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 FEB 2021

End time (00:00-23:59)

01:01 (24 HR)

AE End Date and Time (derived)

19 FEB 2021 01:01

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 17:27:45

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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	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 17:27:45

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AEID

Adverse event

EXACERBATION OF
ORTHOSTATIC HYPOTENSION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 FEB 2021

Start time (00:00-23:59)

01:00 (24 HR)

AE start date and time (derived)

19 FEB 2021 01:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 17:27:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 21:25:58

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:25:57

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Name of Medication ACETYLSALICYLIC ACID

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1980	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:25:57

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Name of Medication CALCIUM PLUS D3
(CALCIUM/VITAMIN D3)

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 600/800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:25:57

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 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 (3)

Data signed: (b) (4) 05 Apr 2021 21:25:57

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Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐
No ☒

Indication MILD CONSTIPATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:25:57

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 (4)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
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 (5)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input 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"/>

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

Name of Medication PLATELET TRANSFUSION

Prophylaxis Yes ☐
No ☒

Indication THROMBOCYTOPENIA

Dose per administration 1

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

If dose unit is Other, specify UNIT

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

If frequency is Other, specify THREE TIMES

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

Name of Medication MIDODRINE

Prophylaxis Yes ☐
No ☒

Indication ORTHOSTATIC HYPOTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐
No ☒

Indication EXACERBATION OF
ORTHOSTATIC HYPOTENSION

Dose per administration 0.6

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

If dose unit is Other, specify MCG/ KG

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 EVERY MINUTE

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 21:25:57

Generated On: 09 Jun 2021 17:03:13

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 21:25:58

Generated On: 09 Jun 2021 17:03:13

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Apr 2021 19:46:16

Generated On: 09 Jun 2021 17:03:13

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
19 FEB 2021	STAPLES TO HEAD	Adverse Event	
23 FEB 2021	BONE MARROW BIOPSY	Adverse Event	

US3312224

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:03:13

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

US3312224

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:13

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 ☐

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:58:42

Generated On: 09 Jun 2021 17:03:13

SAEID	USA-US300-2021-MRNA-1273-P301000018
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:58:42

Generated On: 09 Jun 2021 17:03:13

SAEID	USA-US300-2021-MRNA-1273-P301000018
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/FEB/2021 09:18
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

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:58:42

Generated On: 09 Jun 2021 17:03:13

SAEID	USA-US300-2021-MRNA-1273-P301000018
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/MAR/2021 18:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:58:42

Generated On: 09 Jun 2021 17:03:13

SAEID	USA-US300-2021-MRNA-1273-P301000018
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	26/MAR/2021 13:10
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

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:58:42

Generated On: 09 Jun 2021 17:03:13

SAEID	USA-US300-2021-MRNA-1273-P301000018
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	05/APR/2021 12:24
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

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 21:58:42

Generated On: 09 Jun 2021 17:03:13

SAEID	USA-US300-2021-MRNA-1273-P301000018
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/APR/2021 06:32
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

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 21:58:42

Generated On: 09 Jun 2021 17:03:13

SAEID	USA-US300-2021-MRNA-1273-P301000018
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	09/APR/2021 09:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 21:58:42

Generated On: 09 Jun 2021 17:03:13

SAEID	USA-US300-2021-MRNA-1273-P301000018
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/APR/2021 05:57
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

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 21:58:42

Generated On: 09 Jun 2021 17:03:13

SAEID	USA-US300-2021-MRNA-1273-P301000018
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	27/APR/2021 09:12
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

US3312224 (Prod: Johnson County Clin-Trials)

US3312224

Form: Participant Creation

Generated On: 09 Jun 2021 17:03:13

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'US3312224'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 13:34:30

US3312224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:06:41

US3312224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 13:34:31

US3312224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	24 Aug 2020 15:06:41

US3312224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'SCRN'	System	24 Aug 2020 15:06:41

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered (b) (6) 1936'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 13:34:32

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User closed query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:30:11
Query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' answered with 'completed' (Site from DM).	Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:58
User entered '84'	Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46
User opened query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 06:52:21

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'YEARS'	System	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '84'	System	24 Aug 2020 15:07:05

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Male (M)'	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'I'	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:13

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	28 Aug 2020 20:35:46

US3312224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:13

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 Aug 2020'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:07:05

US3312224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Aug 2020'	System	24 Aug 2020 15:07:05

US3312224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2020'	System	24 Aug 2020 15:07:05

US3312224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:13

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4)	24 Aug 2020 15:07:05

US3312224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Aug 2020 15:07:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 15:07:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Christa Estrada (b) (4)	24 Aug 2020 15:07:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Aug 2020 15:07:05
User entered empty.	System	24 Aug 2020 15:07:05
	Christa Estrada (b) (4)	24 Aug 2020 15:07:05
	(b) (4)	

US3312224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:13

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:07:05

US3312224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:13

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:07:05

US3312224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:13

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:07:05

US3312224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:13

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 13:34:31

US3312224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:13

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'I'	System	24 Aug 2020 15:07:25

US3312224

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	Christa Estrada (b) (4)	24 Aug 2020 15:07:25

US3312224

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:03:13

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:01:19

US3312224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 18:03:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 18:03:04
Data point term sent to Coder	System	02 Sep 2020 18:02:02
User entered 'hypertension'	Karol Moore (b) (4)	02 Sep 2020 18:01:51

US3312224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'un UNK 2005'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:01:51

US3312224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:01:51

US3312224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:01:51

US3312224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:01:51

US3312224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:01:51

US3312224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2005'	System	02 Sep 2020 18:01:51

US3312224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2005'	System	02 Sep 2020 18:01:51

US3312224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Sep 2020 18:01:51

US3312224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Sep 2020 18:01:51

US3312224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 18:03:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 18:03:51
Data point term sent to Coder	System	02 Sep 2020 18:03:03
User entered 'hyperlipidemia'	Karol Moore (b) (4)	02 Sep 2020 18:02:03

US3312224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'un UNK 2005'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3312224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3312224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 18:02:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 18:02:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	02 Sep 2020 18:02:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 18:02:03
User entered empty.	System	02 Sep 2020 18:02:03
	Karol Moore (b) (4)	02 Sep 2020 18:02:03
	(b) (4)	

US3312224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3312224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:02:03

US3312224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2005'	System	02 Sep 2020 18:02:03

US3312224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2005'	System	02 Sep 2020 18:02:03

US3312224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Sep 2020 18:02:03

US3312224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Sep 2020 18:02:03

US3312224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
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)	20 Oct 2020 16:46:14
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 'ASSOCIATED CONDITION VERIFIED AND UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:10:24
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)	16 Oct 2020 06:39:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Coronary artery bypass graft - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:39:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:39:50
Data point term sent to Coder	System	02 Sep 2020 18:07:16
User entered 'Coronary artery bypass grafting x3 vessels'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:16

US3312224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'un UNK 2005'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:16

US3312224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:16

US3312224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:16

US3312224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'un UNK 2005'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:16

US3312224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:16

US3312224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2005'	System	02 Sep 2020 18:06:16

US3312224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2005'	System	02 Sep 2020 18:06:16

US3312224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2005'	System	02 Sep 2020 18:06:16

US3312224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2005'	System	02 Sep 2020 18:06:16

US3312224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 18:07:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 18:07:48
Data point term sent to Coder	System	02 Sep 2020 18:07:16
User entered 'osteoporosis'	Karol Moore (b) (4)	02 Sep 2020 18:06:37

US3312224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'un UNK 2015'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:37

US3312224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:37

US3312224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:37

US3312224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:37

US3312224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:37

US3312224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2015'	System	02 Sep 2020 18:06:37

US3312224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2015'	System	02 Sep 2020 18:06:37

US3312224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Sep 2020 18:06:37

US3312224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Sep 2020 18:06:37

US3312224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 18:07:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 18:07:48
Data point term sent to Coder	System	02 Sep 2020 18:07:18
User entered 'hypothyroidism'	Karol Moore (b) (4)	02 Sep 2020 18:06:50

US3312224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'un UNK 2019'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:50

US3312224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:50

US3312224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:50

US3312224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:50

US3312224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:06:50

US3312224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2019'	System	02 Sep 2020 18:06:50

US3312224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2019'	System	02 Sep 2020 18:06:50

US3312224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Sep 2020 18:06:50

US3312224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Sep 2020 18:06:50

US3312224

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 18:10:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 18:10:45
Data point term sent to Coder	System	02 Sep 2020 18:09:26
User entered 'mild constipation'	Karol Moore (b) (4)	02 Sep 2020 18:08:40

US3312224

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'un UNK 2019'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:08:40

US3312224

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:08:40

US3312224

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:08:40

US3312224

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:08:40

US3312224

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:08:40

US3312224

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2019'	System	02 Sep 2020 18:08:40

US3312224

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2019'	System	02 Sep 2020 18:08:40

US3312224

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Sep 2020 18:08:40

US3312224

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Sep 2020 18:08:40

US3312224

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 02:59:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 02:59:30
Data point term sent to Coder	System	19 Oct 2020 02:58:25
User entered 'SEASONAL ALLERGIES'	Karol Moore (b) (4)	19 Oct 2020 02:58:12

US3312224

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'UN UNK 1950'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:58:12

US3312224

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:58:12

US3312224

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:58:12

US3312224

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:58:12

US3312224

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:58:12

US3312224

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 1950'	System	19 Oct 2020 02:58:12

US3312224

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '1950'	System	19 Oct 2020 02:58:12

US3312224

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	19 Oct 2020 02:58:12

US3312224

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	19 Oct 2020 02:58:12

US3312224

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 03:00:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 03:00:25
Data point term sent to Coder	System	19 Oct 2020 02:59:27
User entered 'HIATAL HERNIA'	Karol Moore (b) (4)	19 Oct 2020 02:58:28

US3312224

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'UN UNK 2015'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:58:28

US3312224

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:58:28

US3312224

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:58:28

US3312224

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 02:58:28

US3312224

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 02:58:28

US3312224

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2015'	System	19 Oct 2020 02:58:28

US3312224

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2015'	System	19 Oct 2020 02:58:28

US3312224

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	19 Oct 2020 02:58:28

US3312224

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	19 Oct 2020 02:58:28

US3312224

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 22:08:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 22:08:26
Data point term sent to Coder	System	19 Oct 2020 22:07:33
User entered 'Coronary Artery Disease'	Karol Moore (b) (4)	19 Oct 2020 22:06:37

US3312224

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'UN UNK 2005'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:06:37

US3312224

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:06:37

US3312224

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 22:06:37

US3312224

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 22:06:37

US3312224

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:06:37

US3312224

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2005'	System	19 Oct 2020 22:06:37

US3312224

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2005'	System	19 Oct 2020 22:06:37

US3312224

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	19 Oct 2020 22:06:37

US3312224

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	19 Oct 2020 22:06:37

US3312224

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:54:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:54:32
Data point term sent to Coder	System	25 Mar 2021 19:53:52
User entered 'PENICILLIN ALLERGY'	Karol Moore (b) (4)	25 Mar 2021 19:52:54

US3312224

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'UN UNK 1950'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:52:54

US3312224

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:52:54

US3312224

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	25 Mar 2021 19:52:54

US3312224

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) Karol Moore (b) (4)	25 Mar 2021 19:52:54

US3312224

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:52:54

US3312224

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 1950'	System	25 Mar 2021 19:52:54

US3312224

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '1950'	System	25 Mar 2021 19:52:54

US3312224

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	25 Mar 2021 19:52:54

US3312224

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	25 Mar 2021 19:52:54

US3312224

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User coded data point as SOC: Vascular disorders, HLT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Orthostatic hypotension, LLT: Orthostatic hypotension - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:54:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:54:32
Data point term sent to Coder	System	25 Mar 2021 19:53:51
User entered 'ORTHOSTATIC HYPOTENSION'	Karol Moore (b) (4)	25 Mar 2021 19:53:35

US3312224

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'UN UNK 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:53:35

US3312224

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:53:35

US3312224

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	25 Mar 2021 19:53:35

US3312224

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) Karol Moore (b) (4)	25 Mar 2021 19:53:35

US3312224

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:53:35

US3312224

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2017'	System	25 Mar 2021 19:53:35

US3312224

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2017'	System	25 Mar 2021 19:53:35

US3312224

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	25 Mar 2021 19:53:35

US3312224

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	25 Mar 2021 19:53:35

US3312224

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Bleeding tendencies, PT: Increased tendency to bruise, LLT: Increased tendency to bruise - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:55:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:55:30
Data point term sent to Coder	System	25 Mar 2021 19:54:52
User entered 'BRUISING EASILY'	Karol Moore (b) (4)	25 Mar 2021 19:54:28

US3312224

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'UN UNK 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:54:28

US3312224

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:54:28

US3312224

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:54:28

US3312224

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) Karol Moore (b) (4)	25 Mar 2021 19:54:28

US3312224

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:54:28

US3312224

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2017'	System	25 Mar 2021 19:54:28

US3312224

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2017'	System	25 Mar 2021 19:54:28

US3312224

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	25 Mar 2021 19:54:28

US3312224

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	25 Mar 2021 19:54:28

US3312224

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytopenias, PT: Thrombocytopenia, LLT: Thrombocytopenia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 12:20:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 12:20:29
Data point term sent to Coder	System	02 Apr 2021 12:19:46
User entered 'thrombocytopenia'	Heather Barker (b) (4)	02 Apr 2021 12:19:22

US3312224

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'un UNK 2017'	(b) (4) Heather Barker (b) (4) (b) (4)	02 Apr 2021 12:19:22

US3312224

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0'	(b) (4) Heather Barker (b) (4) (b) (4)	02 Apr 2021 12:19:22

US3312224

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) Heather Barker (b) (4) (b) (4)	02 Apr 2021 12:19:22

US3312224

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) Heather Barker (b) (4) (b) (4)	02 Apr 2021 12:19:22

US3312224

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0'	(b) (4) Heather Barker (b) (4) (b) (4)	02 Apr 2021 12:19:22

US3312224

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'Jan 2017'	System	02 Apr 2021 12:19:22

US3312224

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '2017'	System	02 Apr 2021 12:19:22

US3312224

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Apr 2021 12:19:22

US3312224

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered empty.	System	02 Apr 2021 12:19:22

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '08:55' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 00:26:12
User entered '8:55'	Karol Moore (b) (4)	02 Sep 2020 18:10:09
	(b) (4)	

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '24 Aug 2020 08:55'	System	15 Sep 2020 00:26:12
User entered '24 Aug 2020 8:55'	System	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '72' in	(b) (4) Karol Moore (b) (4)	02 Sep 2020 18:10:09
DataPoint set to visible.	(b) (4) System	24 Aug 2020 15:07:25

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '170' lb	(b) (4) Karol Moore (b) (4)	02 Sep 2020 18:10:09
DataPoint set to visible.	(b) (4) System	24 Aug 2020 15:07:25

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered '23.10435'	System	02 Sep 2020 18:10:09
DataPoint set to visible.	System	24 Aug 2020 15:07:25

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'kg/m2'	System	02 Sep 2020 18:10:09
DataPoint set to visible.	System	24 Aug 2020 15:07:25

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'bpm'	System	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'breaths/min'	System	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'mmHg'	System	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User entered 'mmHg'	System	02 Sep 2020 18:10:09

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58

US3312224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58

US3312224

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:20

US3312224

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:20

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

[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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

[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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

[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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4)	02 Sep 2020 18:10:55
	Karol Moore (b) (4)	
	(b) (4)	

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

[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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

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 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '0'	(b) (4) Karol Moore (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:04:58
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:10:55

US3312224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:08:14

US3312224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 Aug 2020'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:08:14

US3312224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	24 Aug 2020 15:08:14

US3312224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'VISIT1'	System	24 Aug 2020 15:08:14

US3312224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 14:45:14

US3312224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:13

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '187622'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 14:45:14

US3312224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:13

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 14:45:14

US3312224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:13

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4) (b) (4)	24 Aug 2020 15:08:27

US3312224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:13

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	Christa Estrada (b) (4)	24 Aug 2020 15:08:27

US3312224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:13

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:08:27

US3312224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:13

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:08:27

US3312224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:13

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:08:27

US3312224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:13

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Heather Barker (b) (4)	30 Oct 2020 18:04:46
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:39:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:25:31

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	02 Sep 2020 18:12:03
	(b) (4)	

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '08:55' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 00:26:22
User entered '8:55'	Karol Moore (b) (4)	02 Sep 2020 18:12:03
	(b) (4)	

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered '24 Aug 2020 08:55'	System	15 Sep 2020 00:26:22
User entered '24 Aug 2020 8:55'	System	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '98.2' F	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '68'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'bpm'	System	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'breaths/min'	System	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '116'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'mmHg'	System	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '60'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'mmHg'	System	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:30:43
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 19:25:15
User entered '10:35'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered '24 Aug 2020 10:35'	System	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '98' F	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '61'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'bpm'	System	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'breaths/min'	System	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '114'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'mmHg'	System	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '64'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'mmHg'	System	02 Sep 2020 18:12:03

US3312224

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:09

US3312224

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:09

US3312224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:08:55

US3312224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:08:55

US3312224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:08:55

US3312224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 15:08:55

US3312224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 Aug 2020'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:08:55

US3312224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '10:02'	(b) (4) Christa Estrada (b) (4)	24 Aug 2020 15:08:55

US3312224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered '24 Aug 2020 10:02'	System	24 Aug 2020 15:08:55

US3312224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	24 Aug 2020 15:08:55

US3312224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'ONCE'	System	24 Aug 2020 15:08:55

US3312224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 15:08:55

US3312224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:32

US3312224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:32

US3312224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '09:27' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 00:26:31
User entered '9:27'	Karol Moore (b) (4)	02 Sep 2020 18:12:32
	(b) (4)	

US3312224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:57
User entered '24 Aug 2020 09:27'	System	15 Sep 2020 00:26:31
User entered '24 Aug 2020 9:27'	System	02 Sep 2020 18:12:32

US3312224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:03:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:46

US3312224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:46

US3312224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:46

US3312224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '09:18' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 00:26:38
User entered '9:18'	Karol Moore (b) (4)	02 Sep 2020 18:12:46
	(b) (4)	

US3312224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User entered '24 Aug 2020 09:18'	System	15 Sep 2020 00:26:38
User entered '24 Aug 2020 9:18'	System	02 Sep 2020 18:12:46

US3312224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:46

US3312224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:46

US3312224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:46

US3312224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:13

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User entered empty.	System	02 Sep 2020 18:12:46

US3312224

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:12:49

US3312224

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User entered 'I'	System	02 Sep 2020 18:12:49

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:47:29', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9bc89e1c-77a1-4646-ad8f-3175ec243728' User entered 'Yes (Y)'	System	24 Aug 2020 15:48:11
	System	24 Aug 2020 15:48:11

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:47:46', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9bc89e1c-77a1-4646-ad8f-3175ec243728' User entered '98.0'	System	24 Aug 2020 15:48:11
	System	24 Aug 2020 15:48:11

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:47:54', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9bc89e1c-77a1-4646-ad8f-3175ec243728'	System	24 Aug 2020 15:48:11
User entered 'No (N)'	System	24 Aug 2020 15:48:11

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:48:08', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9bc89e1c-77a1-4646-ad8f-3175ec243728' User entered '24 Aug 2020 10:48'	System	24 Aug 2020 15:48:11
	System	24 Aug 2020 15:48:11

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Aug 2020 10:22'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Aug 2020 12:52'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:29:57', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b72d5257-ea46-4fa5-a317-582cda2743e2'	System	25 Aug 2020 00:32:02
User entered 'Yes (Y)'	System	25 Aug 2020 00:32:02

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:31:38', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b72d5257-ea46-4fa5-a317-582cda2743e2' User entered '97.0'	System	25 Aug 2020 00:32:02
	System	25 Aug 2020 00:32:02

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:31:44', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b72d5257-ea46-4fa5-a317-582cda2743e2'	System	25 Aug 2020 00:32:02
User entered 'No (N)'	System	25 Aug 2020 00:32:02

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:32:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b72d5257-ea46-4fa5-a317-582cda2743e2'	System	25 Aug 2020 00:32:02
User entered '24 Aug 2020 19:32'	System	25 Aug 2020 00:32:02

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Aug 2020 13:47'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 2'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:01:10', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '53b93e0b-cfbe-4287-a846-da0c393a3a3f' User entered 'Yes (Y)'	System	25 Aug 2020 22:04:42
	System	25 Aug 2020 22:04:42

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:04:05', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '53b93e0b-cf8e-4287-a846-da0c393a3a3f' User entered '99.9'	System	25 Aug 2020 22:04:42
	System	25 Aug 2020 22:04:42

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:04:28', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '53b93e0b-cf8e-4287-a846-da0c393a3a3f' User entered 'No (N)'	System	25 Aug 2020 22:04:42
	System	25 Aug 2020 22:04:42

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:04:39', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '53b93e0b-cfbe-4287-a846-da0c393a3a3f' User entered '25 Aug 2020 17:04'	System	25 Aug 2020 22:04:42
	System	25 Aug 2020 22:04:42

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 3'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:14:07', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'db5aa380-b13a-42ba-9cab-b033f311edaf' User entered 'Yes (Y)'	System	26 Aug 2020 21:14:37
	System	26 Aug 2020 21:14:37

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:14:15', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'db5aa380-b13a-42ba-9cab-b033f311edaf' User entered '98.7'	System	26 Aug 2020 21:14:37
	System	26 Aug 2020 21:14:37

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:14:20', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'db5aa380-b13a-42ba-9cab-b033f311edaf'	System	26 Aug 2020 21:14:37
User entered 'No (N)'	System	26 Aug 2020 21:14:37

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:14:35', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'db5aa380-b13a-42ba-9cab-b033f311edaf' User entered '26 Aug 2020 16:14'	System	26 Aug 2020 21:14:37
	System	26 Aug 2020 21:14:37

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 4'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:45:21', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b004e70a-7d93-4769-9a53-6911d8995dc7'	System	27 Aug 2020 21:46:25
User entered 'Yes (Y)'	System	27 Aug 2020 21:46:25

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:45:59', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b004e70a-7d93-4769-9a53-6911d8995dc7' User entered '93.0'	System	27 Aug 2020 21:46:25
	System	27 Aug 2020 21:46:25

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:46:04', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b004e70a-7d93-4769-9a53-6911d8995dc7'	System	27 Aug 2020 21:46:25
User entered 'No (N)'	System	27 Aug 2020 21:46:25

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:46:21', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b004e70a-7d93-4769-9a53-6911d8995dc7' User entered '27 Aug 2020 16:46'	System	27 Aug 2020 21:46:25
	System	27 Aug 2020 21:46:25

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 5'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:26:42', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '943ab4a9-7582-43c1-9f8c-48b8d0f468f4' User entered 'Yes (Y)'	System	28 Aug 2020 21:30:18
	System	28 Aug 2020 21:30:18

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:29:55', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '943ab4a9-7582-43c1-9f8c-48b8d0f468f4' User entered '97.1'	System	28 Aug 2020 21:30:18
	System	28 Aug 2020 21:30:18

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:03', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '943ab4a9-7582-43c1-9f8c-48b8d0f468f4' User entered 'No (N)'	System	28 Aug 2020 21:30:18
	System	28 Aug 2020 21:30:18

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:16', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '943ab4a9-7582-43c1-9f8c-48b8d0f468f4' User entered '28 Aug 2020 16:30'	System	28 Aug 2020 21:30:18
	System	28 Aug 2020 21:30:18

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 6'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:00:58', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a7061117-c0de-482d-9643-baf1012f9885' User entered 'Yes (Y)'	System	29 Aug 2020 21:02:47
	System	29 Aug 2020 21:02:47

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:02:32', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a7061117-c0de-482d-9643-baf1012f9885' User entered '97.5'	System	29 Aug 2020 21:02:47
	System	29 Aug 2020 21:02:47

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:02:38', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a7061117-c0de-482d-9643-baf1012f9885'	System	29 Aug 2020 21:02:47
User entered 'No (N)'	System	29 Aug 2020 21:02:47

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:02:43', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a7061117-c0de-482d-9643-baf1012f9885'	System	29 Aug 2020 21:02:47
User entered '29 Aug 2020 16:02'	System	29 Aug 2020 21:02:47

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 7'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T15:59:10', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a8267468-8279-4410-b14a-1af364d82814' User entered 'Yes (Y)'	System	30 Aug 2020 20:59:34
	System	30 Aug 2020 20:59:34

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T15:59:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a8267468-8279-4410-b14a-1af364d82814' User entered '98.0'	System	30 Aug 2020 20:59:34
	System	30 Aug 2020 20:59:34

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T15:59:25', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a8267468-8279-4410-b14a-1af364d82814' User entered 'No (N)'	System	30 Aug 2020 20:59:34
	System	30 Aug 2020 20:59:34

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T15:59:32', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a8267468-8279-4410-b14a-1af364d82814' User entered '30 Aug 2020 15:59'	System	30 Aug 2020 20:59:34
	System	30 Aug 2020 20:59:34

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:50:14', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd362afb1-bbca-4123-a839-e2682c46eae1' User entered 'None (1)'	System	24 Aug 2020 15:50:44
	System	24 Aug 2020 15:50:44

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:50:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd362afb1-bbca-4123-a839-e2682c46eae1' User entered 'No (N)'	System	24 Aug 2020 15:50:44
	System	24 Aug 2020 15:50:44

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:50:23', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd362afb1-bbca-4123-a839-e2682c46eae1' User entered 'No (N)'	System	24 Aug 2020 15:50:44
	System	24 Aug 2020 15:50:44

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:50:29', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd362afb1-bbca-4123-a839-e2682c46eae1' User entered 'None (1)'	System	24 Aug 2020 15:50:44
	System	24 Aug 2020 15:50:44

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:50:42', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd362afb1-bbca-4123-a839-e2682c46eae1' User entered '24 Aug 2020 10:50'	System	24 Aug 2020 15:50:44
	System	24 Aug 2020 15:50:44

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Aug 2020 10:22'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Aug 2020 12:52'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:32:13', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a5ac5aa0-0ce7-4733-9e4a-374f88ed8ff6'	System	25 Aug 2020 00:32:45
User entered 'None (1)'	System	25 Aug 2020 00:32:45

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:32:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a5ac5aa0-0ce7-4733-9e4a-374f88ed8ff6'	System	25 Aug 2020 00:32:45
User entered 'No (N)'	System	25 Aug 2020 00:32:45

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:32:28', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a5ac5aa0-0ce7-4733-9e4a-374f88ed8ff6'	System	25 Aug 2020 00:32:45
User entered 'No (N)'	System	25 Aug 2020 00:32:45

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:32:35', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a5ac5aa0-0ce7-4733-9e4a-374f88ed8ff6' User entered 'None (1)'	System	25 Aug 2020 00:32:45
	System	25 Aug 2020 00:32:45

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:32:43', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a5ac5aa0-0ce7-4733-9e4a-374f88ed8ff6'	System	25 Aug 2020 00:32:45
User entered '24 Aug 2020 19:32'	System	25 Aug 2020 00:32:45

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Aug 2020 13:47'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 2'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:04:52', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1b67b4b5-3034-4117-8630-224ff4286502'	System	25 Aug 2020 22:05:24
User entered 'None (1)'	System	25 Aug 2020 22:05:24

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:05:01', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1b67b4b5-3034-4117-8630-224ff4286502'	System	25 Aug 2020 22:05:24
User entered 'No (N)'	System	25 Aug 2020 22:05:24

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:05:05', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1b67b4b5-3034-4117-8630-224ff4286502'	System	25 Aug 2020 22:05:24
User entered 'No (N)'	System	25 Aug 2020 22:05:24

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:05:09', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1b67b4b5-3034-4117-8630-224ff4286502'	System	25 Aug 2020 22:05:24
User entered 'None (1)'	System	25 Aug 2020 22:05:24

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:05:22', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1b67b4b5-3034-4117-8630-224ff4286502'	System	25 Aug 2020 22:05:24
User entered '25 Aug 2020 17:05'	System	25 Aug 2020 22:05:24

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 3'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:14:43', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '140c3ac8-0d03-44a2-a1d9-eea1017014b9'	System	26 Aug 2020 21:15:13
User entered 'None (1)'	System	26 Aug 2020 21:15:13

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:14:49', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '140c3ac8-0d03-44a2-a1d9-eea1017014b9'	System	26 Aug 2020 21:15:13
User entered 'No (N)'	System	26 Aug 2020 21:15:13

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:14:55', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '140c3ac8-0d03-44a2-a1d9-eea1017014b9'	System	26 Aug 2020 21:15:13
User entered 'No (N)'	System	26 Aug 2020 21:15:13

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:15:06', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '140c3ac8-0d03-44a2-a1d9-eea1017014b9'	System	26 Aug 2020 21:15:13
User entered 'None (1)'	System	26 Aug 2020 21:15:13

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:15:11', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '140c3ac8-0d03-44a2-a1d9-eea1017014b9' User entered '26 Aug 2020 16:15'	System	26 Aug 2020 21:15:13
	System	26 Aug 2020 21:15:13

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 4'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:46:31', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '04db5479-e425-4fe7-ac98-0d848bed408c' User entered 'None (1)'	System	27 Aug 2020 21:46:54
	System	27 Aug 2020 21:46:54

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:46:36', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '04db5479-e425-4fe7-ac98-0d848bed408c' User entered 'No (N)'	System	27 Aug 2020 21:46:54
	System	27 Aug 2020 21:46:54

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:46:40', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '04db5479-e425-4fe7-ac98-0d848bed408c' User entered 'No (N)'	System	27 Aug 2020 21:46:54
	System	27 Aug 2020 21:46:54

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:46:44', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '04db5479-e425-4fe7-ac98-0d848bed408c' User entered 'None (1)'	System	27 Aug 2020 21:46:54
	System	27 Aug 2020 21:46:54

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:46:50', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '04db5479-e425-4fe7-ac98-0d848bed408c' User entered '27 Aug 2020 16:46'	System	27 Aug 2020 21:46:54
	System	27 Aug 2020 21:46:54

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 5'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:21', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a7d4b254-88d0-446c-a1fa-79f69f5d5c5e'	System	28 Aug 2020 21:30:40
User entered 'None (1)'	System	28 Aug 2020 21:30:40

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:25', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a7d4b254-88d0-446c-a1fa-79f69f5d5c5e'	System	28 Aug 2020 21:30:40
User entered 'No (N)'	System	28 Aug 2020 21:30:40

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:28', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a7d4b254-88d0-446c-a1fa-79f69f5d5c5e'	System	28 Aug 2020 21:30:40
User entered 'No (N)'	System	28 Aug 2020 21:30:40

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:32', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a7d4b254-88d0-446c-a1fa-79f69f5d5c5e'	System	28 Aug 2020 21:30:40
User entered 'None (1)'	System	28 Aug 2020 21:30:40

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:37', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a7d4b254-88d0-446c-a1fa-79f69f5d5c5e'	System	28 Aug 2020 21:30:40
User entered '28 Aug 2020 16:30'	System	28 Aug 2020 21:30:40

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 6'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:02:48', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1ea54f24-921b-477e-8455-a6fa53c8c870'	System	29 Aug 2020 21:03:15
User entered 'None (1)'	System	29 Aug 2020 21:03:15

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:02:56', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1ea54f24-921b-477e-8455-a6fa53c8c870'	System	29 Aug 2020 21:03:15
User entered 'No (N)'	System	29 Aug 2020 21:03:15

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1ea54f24-921b-477e-8455-a6fa53c8c870'	System	29 Aug 2020 21:03:15
User entered 'No (N)'	System	29 Aug 2020 21:03:15

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:08', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1ea54f24-921b-477e-8455-a6fa53c8c870'	System	29 Aug 2020 21:03:15
User entered 'None (1)'	System	29 Aug 2020 21:03:15

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:12', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1ea54f24-921b-477e-8455-a6fa53c8c870' User entered '29 Aug 2020 16:03'	System	29 Aug 2020 21:03:15
	System	29 Aug 2020 21:03:15

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 7'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T15:59:38', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c574a4a2-91b2-4787-9633-f87ab4d7add'	System	30 Aug 2020 21:00:05
User entered 'None (1)'	System	30 Aug 2020 21:00:05

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T15:59:44', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c574a4a2-91b2-4787-9633-f87ab4d7add'	System	30 Aug 2020 21:00:05
User entered 'No (N)'	System	30 Aug 2020 21:00:05

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T15:59:48', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c574a4a2-91b2-4787-9633-f87ab4d7add'	System	30 Aug 2020 21:00:05
User entered 'No (N)'	System	30 Aug 2020 21:00:05

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T15:59:55', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c574a4a2-91b2-4787-9633-f87ab4d7add'	System	30 Aug 2020 21:00:05
User entered 'None (1)'	System	30 Aug 2020 21:00:05

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T16:00:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c574a4a2-91b2-4787-9633-f87ab4d7add'	System	30 Aug 2020 21:00:05
User entered '30 Aug 2020 16:00'	System	30 Aug 2020 21:00:05

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:50:58', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3ccdaaa3-469c-4a48-8453-cc386eceae6e' User entered 'None (0)'	System	24 Aug 2020 15:51:59
	System	24 Aug 2020 15:51:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:51:06', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3ccdaaa3-469c-4a48-8453-cc386eceae6e' User entered 'None (0)'	System	24 Aug 2020 15:51:59
	System	24 Aug 2020 15:51:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:51:14', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3ccdada3-469c-4a48-8453-cc386ecea6e'	System	24 Aug 2020 15:51:59
User entered 'None (0)'	System	24 Aug 2020 15:51:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:51:23', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3ccdada3-469c-4a48-8453-cc386ecea6e' User entered 'None (0)'	System	24 Aug 2020 15:51:59
	System	24 Aug 2020 15:51:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:51:28', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3ccdada3-469c-4a48-8453-cc386ecea6e' User entered 'None (0)'	System	24 Aug 2020 15:51:59
	System	24 Aug 2020 15:51:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:51:31', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3ccdada3-469c-4a48-8453-cc386ecea6e'	System	24 Aug 2020 15:51:59
User entered 'None (0)'	System	24 Aug 2020 15:51:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:51:47', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3ccdada3-469c-4a48-8453-cc386eceae6e' User entered 'No (N)'	System	24 Aug 2020 15:51:59
	System	24 Aug 2020 15:51:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T10:51:55', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3ccdada3-469c-4a48-8453-cc386ecea6e'	System	24 Aug 2020 15:51:59
User entered '24 Aug 2020 10:51'	System	24 Aug 2020 15:51:59

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Aug 2020 10:22'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Aug 2020 12:52'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:32:57', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9fa5d51d-b4a7-4f87-b04b-6eb7ce2c9036' User entered 'None (0)'	System	25 Aug 2020 00:33:31
	System	25 Aug 2020 00:33:31

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:33:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9fa5d51d-b4a7-4f87-b04b-6eb7ce2c9036' User entered 'None (0)'	System	25 Aug 2020 00:33:31
	System	25 Aug 2020 00:33:31

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:33:03', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9fa5d51d-b4a7-4f87-b04b-6eb7ce2c9036' User entered 'None (0)'	System	25 Aug 2020 00:33:31
	System	25 Aug 2020 00:33:31

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:33:06', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9fa5d51d-b4a7-4f87-b04b-6eb7ce2c9036' User entered 'None (0)'	System	25 Aug 2020 00:33:31
	System	25 Aug 2020 00:33:31

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:33:09', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9fa5d51d-b4a7-4f87-b04b-6eb7ce2c9036' User entered 'None (0)'	System	25 Aug 2020 00:33:31
	System	25 Aug 2020 00:33:31

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:33:12', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9fa5d51d-b4a7-4f87-b04b-6eb7ce2c9036'	System	25 Aug 2020 00:33:31
User entered 'None (0)'	System	25 Aug 2020 00:33:31

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:33:21', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9fa5d51d-b4a7-4f87-b04b-6eb7ce2c9036'	System	25 Aug 2020 00:33:31
User entered 'No (N)'	System	25 Aug 2020 00:33:31

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-24T19:33:29', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9fa5d51d-b4a7-4f87-b04b-6eb7ce2c9036'	System	25 Aug 2020 00:33:31
User entered '24 Aug 2020 19:33'	System	25 Aug 2020 00:33:31

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Aug 2020 13:47'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 2'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:05:57', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'dc416adf-462d-4c40-9b68-62491eadbfed' User entered 'None (0)'	System	25 Aug 2020 22:06:28
	System	25 Aug 2020 22:06:28

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:06:01', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'dc416adf-462d-4c40-9b68-62491eadbfed' User entered 'None (0)'	System	25 Aug 2020 22:06:28
	System	25 Aug 2020 22:06:28

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:06:06', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'dc416adf-462d-4c40-9b68-62491eadbfed' User entered 'None (0)'	System	25 Aug 2020 22:06:28
	System	25 Aug 2020 22:06:28

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:06:09', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'dc416adf-462d-4c40-9b68-62491eadbfed' User entered 'None (0)'	System	25 Aug 2020 22:06:28
	System	25 Aug 2020 22:06:28

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:06:12', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'dc416adf-462d-4c40-9b68-62491eadbfed' User entered 'None (0)'	System	25 Aug 2020 22:06:28
	System	25 Aug 2020 22:06:28

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:06:15', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'dc416adf-462d-4c40-9b68-62491eadbfed' User entered 'None (0)'	System	25 Aug 2020 22:06:28
	System	25 Aug 2020 22:06:28

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:06:20', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'dc416adf-462d-4c40-9b68-62491eadbfed' User entered 'No (N)'	System	25 Aug 2020 22:06:28
	System	25 Aug 2020 22:06:28

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-25T17:06:25', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'dc416adf-462d-4c40-9b68-62491eadbfed' User entered '25 Aug 2020 17:06'	System	25 Aug 2020 22:06:28
	System	25 Aug 2020 22:06:28

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 3'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:15:32', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bd4b646d-f68f-4f5e-96b9-13468a3a0ad9' User entered 'None (0)'	System	26 Aug 2020 21:16:00
	System	26 Aug 2020 21:16:00

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:15:35', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bd4b646d-f68f-4f5e-96b9-13468a3a0ad9' User entered 'None (0)'	System	26 Aug 2020 21:16:00
	System	26 Aug 2020 21:16:00

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:15:38', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bd4b646d-f68f-4f5e-96b9-13468a3a0ad9' User entered 'None (0)'	System	26 Aug 2020 21:16:00
	System	26 Aug 2020 21:16:00

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:15:43', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bd4b646d-f68f-4f5e-96b9-13468a3a0ad9' User entered 'None (0)'	System	26 Aug 2020 21:16:00
	System	26 Aug 2020 21:16:00

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:15:46', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bd4b646d-f68f-4f5e-96b9-13468a3a0ad9' User entered 'None (0)'	System	26 Aug 2020 21:16:00
	System	26 Aug 2020 21:16:00

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:15:49', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bd4b646d-f68f-4f5e-96b9-13468a3a0ad9' User entered 'None (0)'	System	26 Aug 2020 21:16:00
	System	26 Aug 2020 21:16:00

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:15:53', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bd4b646d-f68f-4f5e-96b9-13468a3a0ad9' User entered 'No (N)'	System	26 Aug 2020 21:16:00
	System	26 Aug 2020 21:16:00

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-26T16:15:57', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bd4b646d-f68f-4f5e-96b9-13468a3a0ad9' User entered '26 Aug 2020 16:15'	System	26 Aug 2020 21:16:00
	System	26 Aug 2020 21:16:00

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 4'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:46:59', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7451de2a-6be8-4999-8a02-5733c2159a5b' User entered 'None (0)'	System	27 Aug 2020 21:47:27
	System	27 Aug 2020 21:47:27

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:47:01', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7451de2a-6be8-4999-8a02-5733c2159a5b' User entered 'None (0)'	System	27 Aug 2020 21:47:27
	System	27 Aug 2020 21:47:27

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:47:04', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7451de2a-6be8-4999-8a02-5733c2159a5b' User entered 'None (0)'	System	27 Aug 2020 21:47:27
	System	27 Aug 2020 21:47:27

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:47:07', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7451de2a-6be8-4999-8a02-5733c2159a5b' User entered 'None (0)'	System	27 Aug 2020 21:47:27
	System	27 Aug 2020 21:47:27

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:47:10', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7451de2a-6be8-4999-8a02-5733c2159a5b' User entered 'None (0)'	System	27 Aug 2020 21:47:27
	System	27 Aug 2020 21:47:27

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:47:13', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7451de2a-6be8-4999-8a02-5733c2159a5b' User entered 'None (0)'	System	27 Aug 2020 21:47:27
	System	27 Aug 2020 21:47:27

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:47:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7451de2a-6be8-4999-8a02-5733c2159a5b' User entered 'No (N)'	System	27 Aug 2020 21:47:27
	System	27 Aug 2020 21:47:27

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-27T16:47:24', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7451de2a-6be8-4999-8a02-5733c2159a5b' User entered '27 Aug 2020 16:47'	System	27 Aug 2020 21:47:27
	System	27 Aug 2020 21:47:27

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 5'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:47', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c95f9049-93de-46fa-a2ca-9927f41b44ff' User entered 'None (0)'	System	28 Aug 2020 21:31:15
	System	28 Aug 2020 21:31:15

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:50', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c95f9049-93de-46fa-a2ca-9927f41b44ff' User entered 'None (0)'	System	28 Aug 2020 21:31:15
	System	28 Aug 2020 21:31:15

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:53', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c95f9049-93de-46fa-a2ca-9927f41b44ff' User entered 'None (0)'	System	28 Aug 2020 21:31:15
	System	28 Aug 2020 21:31:15

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:55', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c95f9049-93de-46fa-a2ca-9927f41b44ff' User entered 'None (0)'	System	28 Aug 2020 21:31:15
	System	28 Aug 2020 21:31:15

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:30:58', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c95f9049-93de-46fa-a2ca-9927f41b44ff' User entered 'None (0)'	System	28 Aug 2020 21:31:15
	System	28 Aug 2020 21:31:15

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:31:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c95f9049-93de-46fa-a2ca-9927f41b44ff' User entered 'None (0)'	System	28 Aug 2020 21:31:15
	System	28 Aug 2020 21:31:15

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:31:05', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c95f9049-93de-46fa-a2ca-9927f41b44ff' User entered 'No (N)'	System	28 Aug 2020 21:31:15
	System	28 Aug 2020 21:31:15

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-28T16:31:10', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c95f9049-93de-46fa-a2ca-9927f41b44ff' User entered '28 Aug 2020 16:31'	System	28 Aug 2020 21:31:15
	System	28 Aug 2020 21:31:15

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 6'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '86512234-2385-4d3a-948a-9595a105aa8c' User entered 'None (0)'	System	29 Aug 2020 21:03:46
	System	29 Aug 2020 21:03:46

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:22', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '86512234-2385-4d3a-948a-9595a105aa8c' User entered 'None (0)'	System	29 Aug 2020 21:03:46
	System	29 Aug 2020 21:03:46

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:25', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '86512234-2385-4d3a-948a-9595a105aa8c' User entered 'None (0)'	System	29 Aug 2020 21:03:46
	System	29 Aug 2020 21:03:46

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:29', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '86512234-2385-4d3a-948a-9595a105aa8c' User entered 'None (0)'	System	29 Aug 2020 21:03:46
	System	29 Aug 2020 21:03:46

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:32', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '86512234-2385-4d3a-948a-9595a105aa8c' User entered 'None (0)'	System	29 Aug 2020 21:03:46
	System	29 Aug 2020 21:03:46

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:34', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '86512234-2385-4d3a-948a-9595a105aa8c' User entered 'None (0)'	System	29 Aug 2020 21:03:46
	System	29 Aug 2020 21:03:46

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:40', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '86512234-2385-4d3a-948a-9595a105aa8c' User entered 'No (N)'	System	29 Aug 2020 21:03:46
	System	29 Aug 2020 21:03:46

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-29T16:03:45', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '86512234-2385-4d3a-948a-9595a105aa8c' User entered '29 Aug 2020 16:03'	System	29 Aug 2020 21:03:46
	System	29 Aug 2020 21:03:46

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 7'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T16:00:08', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'af207525-d3e8-491b-8add-a3ef78347269' User entered 'None (0)'	System	30 Aug 2020 21:00:38
	System	30 Aug 2020 21:00:38

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T16:00:11', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'af207525-d3e8-491b-8add-a3ef78347269' User entered 'None (0)'	System	30 Aug 2020 21:00:38
	System	30 Aug 2020 21:00:38

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T16:00:14', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'af207525-d3e8-491b-8add-a3ef78347269' User entered 'None (0)'	System	30 Aug 2020 21:00:38
	System	30 Aug 2020 21:00:38

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T16:00:17', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'af207525-d3e8-491b-8add-a3ef78347269' User entered 'None (0)'	System	30 Aug 2020 21:00:38
	System	30 Aug 2020 21:00:38

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T16:00:21', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'af207525-d3e8-491b-8add-a3ef78347269' User entered 'None (0)'	System	30 Aug 2020 21:00:38
	System	30 Aug 2020 21:00:38

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T16:00:23', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'af207525-d3e8-491b-8add-a3ef78347269' User entered 'None (0)'	System	30 Aug 2020 21:00:38
	System	30 Aug 2020 21:00:38

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T16:00:28', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'af207525-d3e8-491b-8add-a3ef78347269'	System	30 Aug 2020 21:00:38
User entered 'No (N)'	System	30 Aug 2020 21:00:38

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-08-30T16:00:34', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'af207525-d3e8-491b-8add-a3ef78347269' User entered '30 Aug 2020 16:00'	System	30 Aug 2020 21:00:38
	System	30 Aug 2020 21:00:38

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 15:08:55

US3312224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:13:09

US3312224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '31 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:13:09

US3312224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:13:09

US3312224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4)	02 Sep 2020 18:13:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312224

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:13:12

US3312224

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User entered 'I'	System	02 Sep 2020 18:13:12

US3312224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:26:55

US3312224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '7 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:26:55

US3312224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:26:55

US3312224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4)	15 Sep 2020 00:26:55
	Karol Moore (b) (4)	
	(b) (4)	

US3312224

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	15 Sep 2020 00:27:01

US3312224

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:47
User entered 'I'	System	15 Sep 2020 00:27:01

US3312224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 00:27:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '14 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:27:10

US3312224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Sep 2020 00:27:10

US3312224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4)	15 Sep 2020 00:27:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312224

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 00:27:13
	Karol Moore (b) (4)	
	(b) (4)	

US3312224

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:45:11
User entered '1'	System	15 Sep 2020 00:27:13

US3312224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
Query 'Per CDM: Please complete remaining V2 forms. ' canceled (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 01:55:15
User opened query 'Per CDM: Please complete remaining V2 forms. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 01:42:03
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Sep 2020 15:08:32
	(b) (4)	

US3312224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 15:08:32

US3312224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[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 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 15:08:32

US3312224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'VISIT2'	System	21 Sep 2020 15:08:32

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '08:49'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered '21 Sep 2020 08:49'	System	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '97.5' F	(b) (4) Karol Moore (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '59'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'bpm'	System	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'breaths/min'	System	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '124'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'mmHg'	System	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '69'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'mmHg'	System	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '10:36'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered '21 Sep 2020 10:36'	System	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '97.6' F	(b) (4) Karol Moore (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '60'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'bpm'	System	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'breaths/min'	System	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '116'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'mmHg'	System	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '66'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'mmHg'	System	19 Oct 2020 03:00:22

US3312224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:28

US3312224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:28

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User closed query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; PHYSICAL EXAMINATION; IMMUNOGENICITY; and NASOPHARYNGEAL SWAB' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 07:55:51
Query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; PHYSICAL EXAMINATION; IMMUNOGENICITY; and NASOPHARYNGEAL SWAB' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:33
User opened query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; PHYSICAL EXAMINATION; IMMUNOGENICITY; and NASOPHARYNGEAL SWAB' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 01:55:27
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 15:08:59

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 15:08:59

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Sep 2020 15:08:59

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 15:08:59

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 15:08:59

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '10:05'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 15:08:59

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered '21 Sep 2020 10:05'	System	21 Sep 2020 15:08:59

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 15:08:59

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'ONCE'	System	21 Sep 2020 15:08:59

US3312224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 15:08:59

US3312224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 03:00:44

US3312224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4)	19 Oct 2020 03:00:44

US3312224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '09:27'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:44

US3312224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered '21 Sep 2020 09:27'	System	19 Oct 2020 03:00:44

US3312224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:03:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '21 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:56

US3312224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:56

US3312224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:56

US3312224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:13

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '09:12'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:56

US3312224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered '21 Sep 2020 09:12'	System	19 Oct 2020 03:00:56

US3312224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:56

US3312224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:56

US3312224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:00:56

US3312224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered empty.	System	19 Oct 2020 03:00:56

US3312224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 15:09:04

US3312224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'I'	System	21 Sep 2020 15:09:04

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:45:15', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ded76453-48fe-4b22-911b-42dccfed66d4' User entered 'Yes (Y)'	System	21 Sep 2020 15:45:59
	System	21 Sep 2020 15:45:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:45:41', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ded76453-48fe-4b22-911b-42dccfed66d4' User entered '97.6'	System	21 Sep 2020 15:45:59
	System	21 Sep 2020 15:45:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:45:46', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ded76453-48fe-4b22-911b-42dccfed66d4'	System	21 Sep 2020 15:45:59
User entered 'No (N)'	System	21 Sep 2020 15:45:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:45:55', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ded76453-48fe-4b22-911b-42dccfed66d4' User entered '21 Sep 2020 10:45'	System	21 Sep 2020 15:45:59
	System	21 Sep 2020 15:45:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '21 Sep 2020 10:25'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '21 Sep 2020 12:55'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:00:03', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0f7417de-b5d1-4111-9bf5-5ce74f91902f' User entered 'Yes (Y)'	System	21 Sep 2020 21:00:37
	System	21 Sep 2020 21:00:37

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:00:17', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0f7417de-b5d1-4111-9bf5-5ce74f91902f' User entered '97.7'	System	21 Sep 2020 21:00:37
	System	21 Sep 2020 21:00:37

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:00:23', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0f7417de-b5d1-4111-9bf5-5ce74f91902f' User entered 'No (N)'	System	21 Sep 2020 21:00:37
	System	21 Sep 2020 21:00:37

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:00:32', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0f7417de-b5d1-4111-9bf5-5ce74f91902f' User entered '21 Sep 2020 16:00'	System	21 Sep 2020 21:00:37
	System	21 Sep 2020 21:00:37

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '21 Sep 2020 13:50'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 2'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:12:02', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'f14e5b29-5528-43c8-aebb-bb76da130e70' User entered 'Yes (Y)'	System	22 Sep 2020 21:12:25
	System	22 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:12:10', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'f14e5b29-5528-43c8-aebb-bb76da130e70' User entered '98.3'	System	22 Sep 2020 21:12:25
	System	22 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:12:15', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'f14e5b29-5528-43c8-aebb-bb76da130e70' User entered 'No (N)'	System	22 Sep 2020 21:12:25
	System	22 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:12:21', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'f14e5b29-5528-43c8-aebb-bb76da130e70' User entered '22 Sep 2020 16:12'	System	22 Sep 2020 21:12:25
	System	22 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 3'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:14:58', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0d60921d-5f72-4535-9674-d220a20741c4'	System	23 Sep 2020 21:15:20
User entered 'Yes (Y)'	System	23 Sep 2020 21:15:20

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:15:06', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0d60921d-5f72-4535-9674-d220a20741c4'	System	23 Sep 2020 21:15:20
User entered '98.9'	System	23 Sep 2020 21:15:20

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:15:10', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0d60921d-5f72-4535-9674-d220a20741c4'	System	23 Sep 2020 21:15:20
User entered 'No (N)'	System	23 Sep 2020 21:15:20

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:15:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0d60921d-5f72-4535-9674-d220a20741c4'	System	23 Sep 2020 21:15:20
User entered '23 Sep 2020 16:15'	System	23 Sep 2020 21:15:20

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 4'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:10:54', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c3b2b309-67ab-4e1d-b516-e8c2adf60c67' User entered 'Yes (Y)'	System	24 Sep 2020 21:11:18
	System	24 Sep 2020 21:11:18

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:03', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c3b2b309-67ab-4e1d-b516-e8c2adf60c67' User entered '98.4'	System	24 Sep 2020 21:11:18
	System	24 Sep 2020 21:11:18

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:08', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c3b2b309-67ab-4e1d-b516-e8c2adf60c67'	System	24 Sep 2020 21:11:18
User entered 'No (N)'	System	24 Sep 2020 21:11:18

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:14', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c3b2b309-67ab-4e1d-b516-e8c2adf60c67' User entered '24 Sep 2020 16:11'	System	24 Sep 2020 21:11:18
	System	24 Sep 2020 21:11:18

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 5'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:53:57', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3017aa0b-76d0-42bf-9f55-f00e0242f1c5' User entered 'Yes (Y)'	System	25 Sep 2020 20:57:49
	System	25 Sep 2020 20:57:49

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:57:36', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3017aa0b-76d0-42bf-9f55-f00e0242f1c5' User entered '98.6'	System	25 Sep 2020 20:57:49
	System	25 Sep 2020 20:57:49

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:57:41', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3017aa0b-76d0-42bf-9f55-f00e0242f1c5'	System	25 Sep 2020 20:57:49
User entered 'No (N)'	System	25 Sep 2020 20:57:49

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:57:46', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3017aa0b-76d0-42bf-9f55-f00e0242f1c5' User entered '25 Sep 2020 15:57'	System	25 Sep 2020 20:57:49
	System	25 Sep 2020 20:57:49

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 6'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:34:38', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0b2d9823-88ee-4296-b22e-c18e8781ba23'	System	26 Sep 2020 19:37:44
User entered 'Yes (Y)'	System	26 Sep 2020 19:37:44

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:37:29', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0b2d9823-88ee-4296-b22e-c18e8781ba23' User entered '97.3'	System	26 Sep 2020 19:37:44
	System	26 Sep 2020 19:37:44

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:37:34', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0b2d9823-88ee-4296-b22e-c18e8781ba23'	System	26 Sep 2020 19:37:44
User entered 'No (N)'	System	26 Sep 2020 19:37:44

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:37:39', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0b2d9823-88ee-4296-b22e-c18e8781ba23'	System	26 Sep 2020 19:37:44
User entered '26 Sep 2020 14:37'	System	26 Sep 2020 19:37:44

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 7'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:35:09', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '100f5bf5-bbd9-41d7-ba05-e7e9efbe9e47'	System	27 Sep 2020 19:37:14
User entered 'Yes (Y)'	System	27 Sep 2020 19:37:14

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:37:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '100f5bf5-bbd9-41d7-ba05-e7e9efbe9e47' User entered '97.3'	System	27 Sep 2020 19:37:14
	System	27 Sep 2020 19:37:14

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:37:04', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '100f5bf5-bbd9-41d7-ba05-e7e9efbe9e47'	System	27 Sep 2020 19:37:14
User entered 'No (N)'	System	27 Sep 2020 19:37:14

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:37:09', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '100f5bf5-bbd9-41d7-ba05-e7e9efbe9e47' User entered '27 Sep 2020 14:37'	System	27 Sep 2020 19:37:14
	System	27 Sep 2020 19:37:14

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:07', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd0a11eaf-b3ec-4af2-a374-a6e51a3b7ec9' User entered 'None (1)'	System	21 Sep 2020 15:46:34
	System	21 Sep 2020 15:46:34

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:13', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd0a11eaf-b3ec-4af2-a374-a6e51a3b7ec9' User entered 'No (N)'	System	21 Sep 2020 15:46:34
	System	21 Sep 2020 15:46:34

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:16', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd0a11eaf-b3ec-4af2-a374-a6e51a3b7ec9' User entered 'No (N)'	System	21 Sep 2020 15:46:34
	System	21 Sep 2020 15:46:34

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:23', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd0a11eaf-b3ec-4af2-a374-a6e51a3b7ec9' User entered 'None (1)'	System	21 Sep 2020 15:46:34
	System	21 Sep 2020 15:46:34

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:30', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd0a11eaf-b3ec-4af2-a374-a6e51a3b7ec9' User entered '21 Sep 2020 10:46'	System	21 Sep 2020 15:46:34
	System	21 Sep 2020 15:46:34

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '21 Sep 2020 10:25'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '21 Sep 2020 12:55'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:00:54', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '293d0dd6-4eeb-4c2b-bba5-a351640f6d25'	System	21 Sep 2020 21:04:51
User entered 'None (1)'	System	21 Sep 2020 21:04:51

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:01:06', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '293d0dd6-4eeb-4c2b-bba5-a351640f6d25'	System	21 Sep 2020 21:04:51
User entered 'Yes (Y)'	System	21 Sep 2020 21:04:51

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:02:51', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '293d0dd6-4eeb-4c2b-bba5-a351640f6d25' User entered '5'	System	21 Sep 2020 21:04:51
	System	21 Sep 2020 21:04:51

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:03:33', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '293d0dd6-4eeb-4c2b-bba5-a351640f6d25' User entered 'Yes (Y)'	System	21 Sep 2020 21:04:51
	System	21 Sep 2020 21:04:51

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:03:59', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '293d0dd6-4eeb-4c2b-bba5-a351640f6d25' User entered '5'	System	21 Sep 2020 21:04:51
	System	21 Sep 2020 21:04:51

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:04:07', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '293d0dd6-4eeb-4c2b-bba5-a351640f6d25' User entered 'None (1)'	System	21 Sep 2020 21:04:51
	System	21 Sep 2020 21:04:51

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:04:47', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '293d0dd6-4eeb-4c2b-bba5-a351640f6d25' User entered '21 Sep 2020 16:04'	System	21 Sep 2020 21:04:51
	System	21 Sep 2020 21:04:51

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '21 Sep 2020 13:50'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 2'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:12:32', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1fee1ab6-8623-4945-b8f4-e5e9af995076'	System	22 Sep 2020 21:13:07
User entered 'None (1)'	System	22 Sep 2020 21:13:07

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:12:38', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1fee1ab6-8623-4945-b8f4-e5e9af995076' User entered 'Yes (Y)'	System	22 Sep 2020 21:13:07
	System	22 Sep 2020 21:13:07

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:12:48', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1fee1ab6-8623-4945-b8f4-e5e9af995076' User entered '10'	System	22 Sep 2020 21:13:07
	System	22 Sep 2020 21:13:07

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:12:54', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1fee1ab6-8623-4945-b8f4-e5e9af995076'	System	22 Sep 2020 21:13:07
User entered 'No (N)'	System	22 Sep 2020 21:13:07

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:13:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1fee1ab6-8623-4945-b8f4-e5e9af995076'	System	22 Sep 2020 21:13:07
User entered 'None (1)'	System	22 Sep 2020 21:13:07

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:13:05', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '1fee1ab6-8623-4945-b8f4-e5e9af995076' User entered '22 Sep 2020 16:13'	System	22 Sep 2020 21:13:07
	System	22 Sep 2020 21:13:07

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 3'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:15:26', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '6f6b58c3-a8e9-4aa1-8595-65387c944463'	System	23 Sep 2020 21:15:58
User entered 'None (1)'	System	23 Sep 2020 21:15:58

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:15:30', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '6f6b58c3-a8e9-4aa1-8595-65387c944463' User entered 'Yes (Y)'	System	23 Sep 2020 21:15:58
	System	23 Sep 2020 21:15:58

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:15:37', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '6f6b58c3-a8e9-4aa1-8595-65387c944463' User entered '10'	System	23 Sep 2020 21:15:58
	System	23 Sep 2020 21:15:58

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:15:42', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '6f6b58c3-a8e9-4aa1-8595-65387c944463' User entered 'No (N)'	System	23 Sep 2020 21:15:58
	System	23 Sep 2020 21:15:58

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:15:47', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '6f6b58c3-a8e9-4aa1-8595-65387c944463'	System	23 Sep 2020 21:15:58
User entered 'None (1)'	System	23 Sep 2020 21:15:58

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:15:53', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '6f6b58c3-a8e9-4aa1-8595-65387c944463' User entered '23 Sep 2020 16:15'	System	23 Sep 2020 21:15:58
	System	23 Sep 2020 21:15:58

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 4'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:20', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd53f8e8b-d9a3-40ff-924b-aa7e93804306'	System	24 Sep 2020 21:11:48
User entered 'None (1)'	System	24 Sep 2020 21:11:48

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:24', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd53f8e8b-d9a3-40ff-924b-aa7e93804306'	System	24 Sep 2020 21:11:48
User entered 'Yes (Y)'	System	24 Sep 2020 21:11:48

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:32', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd53f8e8b-d9a3-40ff-924b-aa7e93804306'	System	24 Sep 2020 21:11:48
User entered '10'	System	24 Sep 2020 21:11:48

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:37', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd53f8e8b-d9a3-40ff-924b-aa7e93804306'	System	24 Sep 2020 21:11:48
User entered 'No (N)'	System	24 Sep 2020 21:11:48

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:41', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd53f8e8b-d9a3-40ff-924b-aa7e93804306'	System	24 Sep 2020 21:11:48
User entered 'None (1)'	System	24 Sep 2020 21:11:48

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:46', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd53f8e8b-d9a3-40ff-924b-aa7e93804306'	System	24 Sep 2020 21:11:48
User entered '24 Sep 2020 16:11'	System	24 Sep 2020 21:11:48

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 5'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:57:54', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ed85f5fa-a129-4358-905c-7f3ccc497c8e'	System	25 Sep 2020 20:58:33
User entered 'None (1)'	System	25 Sep 2020 20:58:33

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:57:58', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ed85f5fa-a129-4358-905c-7f3ccc497c8e' User entered 'Yes (Y)'	System	25 Sep 2020 20:58:33
	System	25 Sep 2020 20:58:33

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:58:07', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ed85f5fa-a129-4358-905c-7f3ccc497c8e' User entered '9'	System	25 Sep 2020 20:58:33

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:58:15', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ed85f5fa-a129-4358-905c-7f3ccc497c8e' User entered 'No (N)'	System	25 Sep 2020 20:58:33
	System	25 Sep 2020 20:58:33

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:58:26', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ed85f5fa-a129-4358-905c-7f3ccc497c8e' User entered 'None (1)'	System	25 Sep 2020 20:58:33
	System	25 Sep 2020 20:58:33

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:58:31', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ed85f5fa-a129-4358-905c-7f3ccc497c8e' User entered '25 Sep 2020 15:58'	System	25 Sep 2020 20:58:33
	System	25 Sep 2020 20:58:33

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 6'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:37:46', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '52ea1b1c-fce3-453c-b4cb-7ce495b7d2d3'	System	26 Sep 2020 19:38:17
User entered 'None (1)'	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:37:50', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '52ea1b1c-fce3-453c-b4cb-7ce495b7d2d3'	System	26 Sep 2020 19:38:17
User entered 'Yes (Y)'	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '52ea1b1c-fce3-453c-b4cb-7ce495b7d2d3' User entered '7'	System	26 Sep 2020 19:38:17
	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:04', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '52ea1b1c-fce3-453c-b4cb-7ce495b7d2d3'	System	26 Sep 2020 19:38:17
User entered 'No (N)'	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:09', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '52ea1b1c-fce3-453c-b4cb-7ce495b7d2d3'	System	26 Sep 2020 19:38:17
User entered 'None (1)'	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:13', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '52ea1b1c-fce3-453c-b4cb-7ce495b7d2d3' User entered '26 Sep 2020 14:38'	System	26 Sep 2020 19:38:17
	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 7'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:37:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9417f094-a560-4fb9-b725-417b824af1a8'	System	27 Sep 2020 19:37:52
User entered 'None (1)'	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:37:22', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9417f094-a560-4fb9-b725-417b824af1a8' User entered 'Yes (Y)'	System	27 Sep 2020 19:37:52
	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:37:36', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9417f094-a560-4fb9-b725-417b824af1a8' User entered '7'	System	27 Sep 2020 19:37:52
	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:37:41', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9417f094-a560-4fb9-b725-417b824af1a8' User entered 'No (N)'	System	27 Sep 2020 19:37:52
	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:37:45', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9417f094-a560-4fb9-b725-417b824af1a8' User entered 'None (1)'	System	27 Sep 2020 19:37:52
	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:37:50', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '9417f094-a560-4fb9-b725-417b824af1a8' User entered '27 Sep 2020 14:37'	System	27 Sep 2020 19:37:52
	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:38', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7809448-0df1-4f3f-ae62-d798f3c5cb86' User entered 'None (0)'	System	21 Sep 2020 15:47:14
	System	21 Sep 2020 15:47:14

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:41', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7809448-0df1-4f3f-ae62-d798f3c5cb86' User entered 'None (0)'	System	21 Sep 2020 15:47:14
	System	21 Sep 2020 15:47:14

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:44', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7809448-0df1-4f3f-ae62-d798f3c5cb86' User entered 'None (0)'	System	21 Sep 2020 15:47:14
	System	21 Sep 2020 15:47:14

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:48', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7809448-0df1-4f3f-ae62-d798f3c5cb86' User entered 'None (0)'	System	21 Sep 2020 15:47:14
	System	21 Sep 2020 15:47:14

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:52', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7809448-0df1-4f3f-ae62-d798f3c5cb86' User entered 'None (0)'	System	21 Sep 2020 15:47:14
	System	21 Sep 2020 15:47:14

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:46:55', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7809448-0df1-4f3f-ae62-d798f3c5cb86' User entered 'None (0)'	System	21 Sep 2020 15:47:14
	System	21 Sep 2020 15:47:14

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:47:06', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7809448-0df1-4f3f-ae62-d798f3c5cb86'	System	21 Sep 2020 15:47:14
User entered 'No (N)'	System	21 Sep 2020 15:47:14

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T10:47:11', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7809448-0df1-4f3f-ae62-d798f3c5cb86'	System	21 Sep 2020 15:47:14
User entered '21 Sep 2020 10:47'	System	21 Sep 2020 15:47:14

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '21 Sep 2020 10:25'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '21 Sep 2020 12:55'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:05:29', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e619da1a-bed1-422e-b0be-a6d74adc5d34' User entered 'None (0)'	System	21 Sep 2020 21:05:57
	System	21 Sep 2020 21:05:57

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:05:33', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e619da1a-bed1-422e-b0be-a6d74adc5d34' User entered 'None (0)'	System	21 Sep 2020 21:05:57
	System	21 Sep 2020 21:05:57

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:05:36', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e619da1a-bed1-422e-b0be-a6d74adc5d34' User entered 'None (0)'	System	21 Sep 2020 21:05:57
	System	21 Sep 2020 21:05:57

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:05:39', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e619da1a-bed1-422e-b0be-a6d74adc5d34' User entered 'None (0)'	System	21 Sep 2020 21:05:57
	System	21 Sep 2020 21:05:57

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:05:42', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e619da1a-bed1-422e-b0be-a6d74adc5d34' User entered 'None (0)'	System	21 Sep 2020 21:05:57
	System	21 Sep 2020 21:05:57

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:05:45', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e619da1a-bed1-422e-b0be-a6d74adc5d34' User entered 'None (0)'	System	21 Sep 2020 21:05:57
	System	21 Sep 2020 21:05:57

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:05:50', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e619da1a-bed1-422e-b0be-a6d74adc5d34' User entered 'No (N)'	System	21 Sep 2020 21:05:57
	System	21 Sep 2020 21:05:57

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-21T16:05:55', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e619da1a-bed1-422e-b0be-a6d74adc5d34' User entered '21 Sep 2020 16:05'	System	21 Sep 2020 21:05:57
	System	21 Sep 2020 21:05:57

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '21 Sep 2020 13:50'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 2'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:13:14', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0ac17d50-8dce-4c9f-ab3b-5f617455501a' User entered 'None (0)'	System	22 Sep 2020 21:13:42
	System	22 Sep 2020 21:13:42

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:13:17', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0ac17d50-8dce-4c9f-ab3b-5f617455501a' User entered 'None (0)'	System	22 Sep 2020 21:13:42
	System	22 Sep 2020 21:13:42

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:13:20', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0ac17d50-8dce-4c9f-ab3b-5f617455501a' User entered 'None (0)'	System	22 Sep 2020 21:13:42
	System	22 Sep 2020 21:13:42

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:13:23', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0ac17d50-8dce-4c9f-ab3b-5f617455501a' User entered 'None (0)'	System	22 Sep 2020 21:13:42
	System	22 Sep 2020 21:13:42

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:13:28', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0ac17d50-8dce-4c9f-ab3b-5f617455501a' User entered 'None (0)'	System	22 Sep 2020 21:13:42
	System	22 Sep 2020 21:13:42

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:13:31', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0ac17d50-8dce-4c9f-ab3b-5f617455501a' User entered 'None (0)'	System	22 Sep 2020 21:13:42
	System	22 Sep 2020 21:13:42

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:13:35', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0ac17d50-8dce-4c9f-ab3b-5f617455501a' User entered 'No (N)'	System	22 Sep 2020 21:13:42
	System	22 Sep 2020 21:13:42

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-22T16:13:40', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '0ac17d50-8dce-4c9f-ab3b-5f617455501a' User entered '22 Sep 2020 16:13'	System	22 Sep 2020 21:13:42
	System	22 Sep 2020 21:13:42

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 3'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:16:03', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '84af7e66-7a00-4647-99ea-d0de285601e4' User entered 'None (0)'	System	23 Sep 2020 21:16:30
	System	23 Sep 2020 21:16:30

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:16:06', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '84af7e66-7a00-4647-99ea-d0de285601e4' User entered 'None (0)'	System	23 Sep 2020 21:16:30
	System	23 Sep 2020 21:16:30

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:16:10', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '84af7e66-7a00-4647-99ea-d0de285601e4' User entered 'None (0)'	System	23 Sep 2020 21:16:30
	System	23 Sep 2020 21:16:30

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:16:13', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '84af7e66-7a00-4647-99ea-d0de285601e4' User entered 'None (0)'	System	23 Sep 2020 21:16:30
	System	23 Sep 2020 21:16:30

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:16:16', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '84af7e66-7a00-4647-99ea-d0de285601e4' User entered 'None (0)'	System	23 Sep 2020 21:16:30
	System	23 Sep 2020 21:16:30

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:16:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '84af7e66-7a00-4647-99ea-d0de285601e4' User entered 'None (0)'	System	23 Sep 2020 21:16:30
	System	23 Sep 2020 21:16:30

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:16:24', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '84af7e66-7a00-4647-99ea-d0de285601e4' User entered 'No (N)'	System	23 Sep 2020 21:16:30
	System	23 Sep 2020 21:16:30

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-23T16:16:28', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '84af7e66-7a00-4647-99ea-d0de285601e4' User entered '23 Sep 2020 16:16'	System	23 Sep 2020 21:16:30
	System	23 Sep 2020 21:16:30

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 4'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:55', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '60685f82-c7e2-4095-a770-c2d637ff5e8d' User entered 'None (0)'	System	24 Sep 2020 21:12:25
	System	24 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:11:58', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '60685f82-c7e2-4095-a770-c2d637ff5e8d' User entered 'None (0)'	System	24 Sep 2020 21:12:25
	System	24 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:12:01', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '60685f82-c7e2-4095-a770-c2d637ff5e8d' User entered 'None (0)'	System	24 Sep 2020 21:12:25
	System	24 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:12:05', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '60685f82-c7e2-4095-a770-c2d637ff5e8d' User entered 'None (0)'	System	24 Sep 2020 21:12:25
	System	24 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:12:07', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '60685f82-c7e2-4095-a770-c2d637ff5e8d' User entered 'None (0)'	System	24 Sep 2020 21:12:25
	System	24 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:12:11', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '60685f82-c7e2-4095-a770-c2d637ff5e8d' User entered 'None (0)'	System	24 Sep 2020 21:12:25
	System	24 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:12:16', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '60685f82-c7e2-4095-a770-c2d637ff5e8d' User entered 'No (N)'	System	24 Sep 2020 21:12:25
	System	24 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-24T16:12:20', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '60685f82-c7e2-4095-a770-c2d637ff5e8d' User entered '24 Sep 2020 16:12'	System	24 Sep 2020 21:12:25
	System	24 Sep 2020 21:12:25

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 5'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:58:41', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ebec1171-bf41-4de2-9096-0dfde9c46e00' User entered 'None (0)'	System	25 Sep 2020 20:59:12
	System	25 Sep 2020 20:59:12

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:58:44', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ebec1171-bf41-4de2-9096-0dfde9c46e00' User entered 'None (0)'	System	25 Sep 2020 20:59:12
	System	25 Sep 2020 20:59:12

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:58:49', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ebec1171-bf41-4de2-9096-0dfde9c46e00' User entered 'None (0)'	System	25 Sep 2020 20:59:12
	System	25 Sep 2020 20:59:12

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:58:52', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ebec1171-bf41-4de2-9096-0dfde9c46e00' User entered 'None (0)'	System	25 Sep 2020 20:59:12
	System	25 Sep 2020 20:59:12

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:58:55', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ebec1171-bf41-4de2-9096-0dfde9c46e00' User entered 'None (0)'	System	25 Sep 2020 20:59:12
	System	25 Sep 2020 20:59:12

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:58:59', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ebec1171-bf41-4de2-9096-0dfde9c46e00' User entered 'None (0)'	System	25 Sep 2020 20:59:12
	System	25 Sep 2020 20:59:12

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:59:03', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ebec1171-bf41-4de2-9096-0dfde9c46e00'	System	25 Sep 2020 20:59:12
User entered 'No (N)'	System	25 Sep 2020 20:59:12

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-25T15:59:07', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'ebec1171-bf41-4de2-9096-0dfde9c46e00' User entered '25 Sep 2020 15:59'	System	25 Sep 2020 20:59:12
	System	25 Sep 2020 20:59:12

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 6'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '31b308b8-9779-4c93-8daa-985efded78c1' User entered 'None (0)'	System	26 Sep 2020 19:38:47
	System	26 Sep 2020 19:38:47

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:23', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '31b308b8-9779-4c93-8daa-985efded78c1' User entered 'None (0)'	System	26 Sep 2020 19:38:47
	System	26 Sep 2020 19:38:47

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:26', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '31b308b8-9779-4c93-8daa-985efded78c1' User entered 'None (0)'	System	26 Sep 2020 19:38:47
	System	26 Sep 2020 19:38:47

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:29', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '31b308b8-9779-4c93-8daa-985efded78c1' User entered 'None (0)'	System	26 Sep 2020 19:38:47
	System	26 Sep 2020 19:38:47

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:32', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '31b308b8-9779-4c93-8daa-985efded78c1' User entered 'None (0)'	System	26 Sep 2020 19:38:47
	System	26 Sep 2020 19:38:47

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:35', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '31b308b8-9779-4c93-8daa-985efded78c1' User entered 'None (0)'	System	26 Sep 2020 19:38:47
	System	26 Sep 2020 19:38:47

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:39', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '31b308b8-9779-4c93-8daa-985efded78c1' User entered 'No (N)'	System	26 Sep 2020 19:38:47
	System	26 Sep 2020 19:38:47

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-26T14:38:43', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '31b308b8-9779-4c93-8daa-985efded78c1' User entered '26 Sep 2020 14:38'	System	26 Sep 2020 19:38:47
	System	26 Sep 2020 19:38:47

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	21 Sep 2020 15:08:59
User entered 'Day 7'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:37:58', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7b05614-6ed3-49c3-b970-972b50b1ad25' User entered 'None (0)'	System	27 Sep 2020 19:38:24
	System	27 Sep 2020 19:38:24

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:38:01', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7b05614-6ed3-49c3-b970-972b50b1ad25' User entered 'None (0)'	System	27 Sep 2020 19:38:24
	System	27 Sep 2020 19:38:24

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:38:04', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7b05614-6ed3-49c3-b970-972b50b1ad25' User entered 'None (0)'	System	27 Sep 2020 19:38:24
	System	27 Sep 2020 19:38:24

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:38:07', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7b05614-6ed3-49c3-b970-972b50b1ad25' User entered 'None (0)'	System	27 Sep 2020 19:38:24
	System	27 Sep 2020 19:38:24

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:38:13', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7b05614-6ed3-49c3-b970-972b50b1ad25' User entered 'None (0)'	System	27 Sep 2020 19:38:24
	System	27 Sep 2020 19:38:24

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:38:16', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7b05614-6ed3-49c3-b970-972b50b1ad25' User entered 'None (0)'	System	27 Sep 2020 19:38:24
	System	27 Sep 2020 19:38:24

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:38:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7b05614-6ed3-49c3-b970-972b50b1ad25'	System	27 Sep 2020 19:38:24
User entered 'No (N)'	System	27 Sep 2020 19:38:24

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-27T14:38:23', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b7b05614-6ed3-49c3-b970-972b50b1ad25' User entered '27 Sep 2020 14:38'	System	27 Sep 2020 19:38:24
	System	27 Sep 2020 19:38:24

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 15:08:59

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	26 Sep 2020 19:38:17
User entered 'Day 8'	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-28T16:05:36', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '00bd04b4-e328-4378-9ded-eecad60d6bfb' User entered 'Yes (Y)'	System	28 Sep 2020 21:05:52
	System	28 Sep 2020 21:05:52

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-28T16:05:42', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '00bd04b4-e328-4378-9ded-eecad60d6bfb' User entered '7'	System	28 Sep 2020 21:05:52
	System	28 Sep 2020 21:05:52

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-28T16:05:50', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '00bd04b4-e328-4378-9ded-eecad60d6bfb' User entered '28 Sep 2020 16:05'	System	28 Sep 2020 21:05:52
	System	28 Sep 2020 21:05:52

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	27 Sep 2020 19:37:52
User entered 'Day 9'	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-29T15:48:03', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '38c85bca-d297-4959-8ab2-c1441c8fb45a' User entered 'Yes (Y)'	System	29 Sep 2020 20:48:30
	System	29 Sep 2020 20:48:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-29T15:48:09', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '38c85bca-d297-4959-8ab2-c1441c8fb45a' User entered '7'	System	29 Sep 2020 20:48:30
	System	29 Sep 2020 20:48:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-29T15:48:16', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '38c85bca-d297-4959-8ab2-c1441c8fb45a' User entered '29 Sep 2020 15:48'	System	29 Sep 2020 20:48:30
	System	29 Sep 2020 20:48:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	28 Sep 2020 21:05:52
User entered 'Day 10'	System	28 Sep 2020 21:05:52

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-30T16:11:34', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'eed0ca6e-ea4b-4374-ac26-a5008dfee10e' User entered 'Yes (Y)'	System	30 Sep 2020 21:11:50
	System	30 Sep 2020 21:11:50

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-30T16:11:40', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'eed0ca6e-ea4b-4374-ac26-a5008dfee10e' User entered '7'	System	30 Sep 2020 21:11:50
	System	30 Sep 2020 21:11:50

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-30T16:11:48', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'eed0ca6e-ea4b-4374-ac26-a5008dfee10e' User entered '30 Sep 2020 16:11'	System	30 Sep 2020 21:11:50
	System	30 Sep 2020 21:11:50

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 21:05:52

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 21:05:52

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(11)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	29 Sep 2020 20:48:30
User entered 'Day 11'	System	29 Sep 2020 20:48:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(11)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-01T16:15:18', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '23122634-1827-4ddc-a2fa-404fc9738061' User entered 'Yes (Y)'	System	01 Oct 2020 21:15:40
	System	01 Oct 2020 21:15:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(11)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-01T16:15:33', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '23122634-1827-4ddc-a2fa-404fc9738061' User entered '6'	System	01 Oct 2020 21:15:40
	System	01 Oct 2020 21:15:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(11)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-01T16:15:36', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '23122634-1827-4ddc-a2fa-404fc9738061' User entered '01 Oct 2020 16:15'	System	01 Oct 2020 21:15:40
	System	01 Oct 2020 21:15:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(11)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 20:48:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(11)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 20:48:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(12)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	30 Sep 2020 21:11:50
User entered 'Day 12'	System	30 Sep 2020 21:11:50

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(12)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-02T15:48:47', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bee3b639-d4a3-4936-93d9-12ef333185c8'	System	02 Oct 2020 20:49:28
User entered 'Yes (Y)'	System	02 Oct 2020 20:49:28

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(12)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-02T15:48:52', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bee3b639-d4a3-4936-93d9-12ef333185c8' User entered '6'	System	02 Oct 2020 20:49:28
	System	02 Oct 2020 20:49:28

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(12)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-02T15:48:56', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'bee3b639-d4a3-4936-93d9-12ef333185c8'	System	02 Oct 2020 20:49:28
User entered '02 Oct 2020 15:48'	System	02 Oct 2020 20:49:28

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(12)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 21:11:50

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(12)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 21:11:50

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(13)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	01 Oct 2020 21:15:40
User entered 'Day 13'	System	01 Oct 2020 21:15:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(13)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-03T16:23:54', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7e3e83e5-00d1-480d-b825-56d7d48aeb84' User entered 'Yes (Y)'	System	03 Oct 2020 21:24:07
	System	03 Oct 2020 21:24:07

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(13)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-03T16:24:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7e3e83e5-00d1-480d-b825-56d7d48aeb84' User entered '6'	System	03 Oct 2020 21:24:07
	System	03 Oct 2020 21:24:07

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(13)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-03T16:24:04', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '7e3e83e5-00d1-480d-b825-56d7d48aeb84' User entered '03 Oct 2020 16:24'	System	03 Oct 2020 21:24:07
	System	03 Oct 2020 21:24:07

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(13)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:15:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(13)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:15:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(14)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	02 Oct 2020 20:49:28
User entered 'Day 14'	System	02 Oct 2020 20:49:28

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(14)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-04T14:30:27', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c9e481a3-13e3-4506-afc0-f6fb718afd2d' User entered 'Yes (Y)'	System	04 Oct 2020 19:30:40
	System	04 Oct 2020 19:30:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(14)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-04T14:30:31', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c9e481a3-13e3-4506-afc0-f6fb718afd2d' User entered '5'	System	04 Oct 2020 19:30:40
	System	04 Oct 2020 19:30:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(14)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-04T14:30:36', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c9e481a3-13e3-4506-afc0-f6fb718afd2d' User entered '04 Oct 2020 14:30'	System	04 Oct 2020 19:30:40
	System	04 Oct 2020 19:30:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(14)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:49:28

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(14)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:49:28

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(15)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	03 Oct 2020 21:24:07
User entered 'Day 15'	System	03 Oct 2020 21:24:07

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(15)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-05T16:02:11', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '88dd018d-b67c-4624-8298-5c777e58e6bf' User entered 'Yes (Y)'	System	05 Oct 2020 21:02:23
	System	05 Oct 2020 21:02:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(15)

Generated On: 09 Jun 2021 17:03:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-05T16:02:16', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '88dd018d-b67c-4624-8298-5c777e58e6bf' User entered '5'	System	05 Oct 2020 21:02:23
	System	05 Oct 2020 21:02:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(15)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-05T16:02:21', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '88dd018d-b67c-4624-8298-5c777e58e6bf' User entered '05 Oct 2020 16:02'	System	05 Oct 2020 21:02:23
	System	05 Oct 2020 21:02:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(15)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 21:24:07

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(15)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 21:24:07

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(16)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	04 Oct 2020 19:30:40
User entered 'Day 16'	System	04 Oct 2020 19:30:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(16)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-06T15:42:53', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e384459d-4db9-4a06-8ae2-cb8c18623697' User entered 'Yes (Y)'	System	06 Oct 2020 20:43:09
	System	06 Oct 2020 20:43:09

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(16)

Generated On: 09 Jun 2021 17:03:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-06T15:43:01', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e384459d-4db9-4a06-8ae2-cb8c18623697' User entered '5'	System	06 Oct 2020 20:43:09
	System	06 Oct 2020 20:43:09

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(16)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-06T15:43:05', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e384459d-4db9-4a06-8ae2-cb8c18623697' User entered '06 Oct 2020 15:43'	System	06 Oct 2020 20:43:09
	System	06 Oct 2020 20:43:09

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(16)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 19:30:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(16)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 19:30:40

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(17)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	05 Oct 2020 21:02:23
User entered 'Day 17'	System	05 Oct 2020 21:02:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(17)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-07T14:52:17', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c2b2f20a-06a1-49c4-b737-92e1a2f7fafd' User entered 'Yes (Y)'	System	07 Oct 2020 19:52:30
	System	07 Oct 2020 19:52:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(17)

Generated On: 09 Jun 2021 17:03:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-07T14:52:24', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c2b2f20a-06a1-49c4-b737-92e1a2f7fafd' User entered '4'	System	07 Oct 2020 19:52:30
	System	07 Oct 2020 19:52:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(17)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-07T14:52:28', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c2b2f20a-06a1-49c4-b737-92e1a2f7fafd' User entered '07 Oct 2020 14:52'	System	07 Oct 2020 19:52:30
	System	07 Oct 2020 19:52:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(17)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 21:02:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(17)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 21:02:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(18)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	06 Oct 2020 20:43:09
User entered 'Day 18'	System	06 Oct 2020 20:43:09

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(18)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-08T15:38:40', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '53af1494-8d7e-4287-bdef-4c2fcf1b1194' User entered 'Yes (Y)'	System	08 Oct 2020 20:38:53
	System	08 Oct 2020 20:38:53

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(18)

Generated On: 09 Jun 2021 17:03:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-08T15:38:46', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '53af1494-8d7e-4287-bdef-4c2fcf1b1194' User entered '4'	System	08 Oct 2020 20:38:53
	System	08 Oct 2020 20:38:53

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(18)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-08T15:38:49', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '53af1494-8d7e-4287-bdef-4c2fcf1b1194' User entered '08 Oct 2020 15:38'	System	08 Oct 2020 20:38:53
	System	08 Oct 2020 20:38:53

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(18)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 20:43:09

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(18)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 20:43:09

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(19)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	07 Oct 2020 19:52:30
User entered 'Day 19'	System	07 Oct 2020 19:52:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(19)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-09T15:23:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '55ab6d72-47b9-4edf-b253-fc2156e92c82' User entered 'Yes (Y)'	System	09 Oct 2020 20:23:35
	System	09 Oct 2020 20:23:35

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(19)

Generated On: 09 Jun 2021 17:03:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-09T15:23:26', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '55ab6d72-47b9-4edf-b253-fc2156e92c82' User entered '4'	System	09 Oct 2020 20:23:35
	System	09 Oct 2020 20:23:35

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(19)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-09T15:23:30', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '55ab6d72-47b9-4edf-b253-fc2156e92c82' User entered '09 Oct 2020 15:23'	System	09 Oct 2020 20:23:35
	System	09 Oct 2020 20:23:35

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(19)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 19:52:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(19)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 19:52:30

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(20)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	08 Oct 2020 20:38:53
User entered 'Day 20'	System	08 Oct 2020 20:38:53

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(20)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(20)

Generated On: 09 Jun 2021 17:03:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(20)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(20)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 20:38:53

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(20)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 20:38:53

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(21)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	09 Oct 2020 20:23:35
User entered 'Day 21'	System	09 Oct 2020 20:23:35

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(21)

Generated On: 09 Jun 2021 17:03:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(21)

Generated On: 09 Jun 2021 17:03:13

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(21)

Generated On: 09 Jun 2021 17:03:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(21)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 20:23:35

US3312224

Folder: Diary Dose 2 (1)

Form: Redness_Day(21)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 20:23:35

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	26 Sep 2020 19:38:17
User entered 'Day 8'	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-28T16:06:11', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '88fb10a1-ad5d-4d81-8a7d-55f7370d35a8' User entered 'No (N)'	System	28 Sep 2020 21:06:18
	System	28 Sep 2020 21:06:18

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-28T16:06:16', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '88fb10a1-ad5d-4d81-8a7d-55f7370d35a8' User entered '28 Sep 2020 16:06'	System	28 Sep 2020 21:06:18
	System	28 Sep 2020 21:06:18

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 19:38:17

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	27 Sep 2020 19:37:52
User entered 'Day 9'	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-29T15:48:36', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '697b8dff-5161-4fab-9c0f-e9be129729fa' User entered 'No (N)'	System	29 Sep 2020 20:48:45
	System	29 Sep 2020 20:48:45

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-29T15:48:41', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '697b8dff-5161-4fab-9c0f-e9be129729fa' User entered '29 Sep 2020 15:48'	System	29 Sep 2020 20:48:45
	System	29 Sep 2020 20:48:45

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 19:37:52

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	28 Sep 2020 21:05:52
User entered 'Day 10'	System	28 Sep 2020 21:05:52

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-30T16:12:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '4bf6f039-b1d9-4dcb-907c-0d53aa5acba9' User entered 'No (N)'	System	30 Sep 2020 21:12:10
	System	30 Sep 2020 21:12:10

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-09-30T16:12:07', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '4bf6f039-b1d9-4dcb-907c-0d53aa5acba9' User entered '30 Sep 2020 16:12'	System	30 Sep 2020 21:12:10
	System	30 Sep 2020 21:12:10

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 21:05:52

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 21:05:52

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	29 Sep 2020 20:48:30
User entered 'Day 11'	System	29 Sep 2020 20:48:30

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-01T16:15:44', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'dba56b08-46e0-43ae-a710-3144abef0be3' User entered 'No (N)'	System	01 Oct 2020 21:15:54
	System	01 Oct 2020 21:15:54

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-01T16:15:52', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'dba56b08-46e0-43ae-a710-3144abef0be3' User entered '01 Oct 2020 16:15'	System	01 Oct 2020 21:15:54
	System	01 Oct 2020 21:15:54

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 20:48:30

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 20:48:30

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	30 Sep 2020 21:11:50
User entered 'Day 12'	System	30 Sep 2020 21:11:50

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-02T15:49:10', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3fa485c3-b1d4-4acf-b2e2-e7ee565ab0f5' User entered 'No (N)'	System	02 Oct 2020 20:49:37
	System	02 Oct 2020 20:49:37

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-02T15:49:14', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '3fa485c3-b1d4-4acf-b2e2-e7ee565ab0f5' User entered '02 Oct 2020 15:49'	System	02 Oct 2020 20:49:37
	System	02 Oct 2020 20:49:37

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 21:11:50

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 21:11:50

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	01 Oct 2020 21:15:40
User entered 'Day 13'	System	01 Oct 2020 21:15:40

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-03T16:24:10', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '5a4e1d64-d6f4-4ce3-aff4-fff27e6cef98'	System	03 Oct 2020 21:24:16
User entered 'No (N)'	System	03 Oct 2020 21:24:16

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-03T16:24:13', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '5a4e1d64-d6f4-4ce3-aff4-fff27e6cef98' User entered '03 Oct 2020 16:24'	System	03 Oct 2020 21:24:16
	System	03 Oct 2020 21:24:16

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:15:40

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:15:40

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	02 Oct 2020 20:49:28
User entered 'Day 14'	System	02 Oct 2020 20:49:28

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-04T14:30:46', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '10c80691-cb70-4276-bec9-80d942f1e5c4' User entered 'No (N)'	System	04 Oct 2020 19:30:54
	System	04 Oct 2020 19:30:54

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-04T14:30:50', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '10c80691-cb70-4276-bec9-80d942f1e5c4' User entered '04 Oct 2020 14:30'	System	04 Oct 2020 19:30:54
	System	04 Oct 2020 19:30:54

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:49:28

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:49:28

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	03 Oct 2020 21:24:07
User entered 'Day 15'	System	03 Oct 2020 21:24:07

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-05T16:02:33', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '63a07689-8ef3-430c-abc-f94965dda579' User entered 'No (N)'	System	05 Oct 2020 21:02:42
	System	05 Oct 2020 21:02:42

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-05T16:02:36', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '63a07689-8ef3-430c-abc-f94965dda579' User entered '05 Oct 2020 16:02'	System	05 Oct 2020 21:02:42
	System	05 Oct 2020 21:02:42

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 21:24:07

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 21:24:07

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	04 Oct 2020 19:30:40
User entered 'Day 16'	System	04 Oct 2020 19:30:40

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-06T15:43:17', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '40d9ac1e-3966-4d94-bb3d-d2e22a2484d6' User entered 'No (N)'	System	06 Oct 2020 20:43:23
	System	06 Oct 2020 20:43:23

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-06T15:43:20', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '40d9ac1e-3966-4d94-bb3d-d2e22a2484d6' User entered '06 Oct 2020 15:43'	System	06 Oct 2020 20:43:23
	System	06 Oct 2020 20:43:23

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 19:30:40

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 19:30:40

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	05 Oct 2020 21:02:23
User entered 'Day 17'	System	05 Oct 2020 21:02:23

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-07T14:52:35', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c2c5e672-5e80-43dc-a58a-83a0a5137cfe' User entered 'No (N)'	System	07 Oct 2020 19:52:43
	System	07 Oct 2020 19:52:43

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-07T14:52:39', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c2c5e672-5e80-43dc-a58a-83a0a5137cfe' User entered '07 Oct 2020 14:52'	System	07 Oct 2020 19:52:43
	System	07 Oct 2020 19:52:43

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 21:02:23

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 21:02:23

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	06 Oct 2020 20:43:09
User entered 'Day 18'	System	06 Oct 2020 20:43:09

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-08T15:38:58', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '86e3f784-e01c-49bd-a58a-649a08c8f212' User entered 'No (N)'	System	08 Oct 2020 20:39:05
	System	08 Oct 2020 20:39:05

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-08T15:39:01', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '86e3f784-e01c-49bd-a58a-649a08c8f212' User entered '08 Oct 2020 15:39'	System	08 Oct 2020 20:39:05
	System	08 Oct 2020 20:39:05

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 20:43:09

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 20:43:09

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	07 Oct 2020 19:52:30
User entered 'Day 19'	System	07 Oct 2020 19:52:30

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-09T15:23:36', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '97aedebe-27ff-48c9-8bc5-aaf8d2f3721c' User entered 'No (N)'	System	09 Oct 2020 20:23:42
	System	09 Oct 2020 20:23:42

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-09T15:23:40', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '97aedebea-27ff-48c9-8bc5-aaf8d2f3721c' User entered '09 Oct 2020 15:23'	System	09 Oct 2020 20:23:42
	System	09 Oct 2020 20:23:42

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 19:52:30

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 19:52:30

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	08 Oct 2020 20:38:53
User entered 'Day 20'	System	08 Oct 2020 20:38:53

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 20:38:53

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 20:38:53

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	09 Oct 2020 20:23:35
User entered 'Day 21'	System	09 Oct 2020 20:23:35

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:03:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:03:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:03:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 20:23:35

US3312224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:03:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 20:23:35

US3312224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:01:27

US3312224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '30 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:01:27

US3312224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:01:27

US3312224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:01:27

US3312224

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:01:30

US3312224

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'I'	System	19 Oct 2020 03:01:30

US3312224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:01:47

US3312224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '05 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:01:47

US3312224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:01:47

US3312224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4)	19 Oct 2020 03:01:47
	Karol Moore (b) (4)	
	(b) (4)	

US3312224

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:01:58

US3312224

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'I'	System	19 Oct 2020 03:01:58

US3312224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:02:59

US3312224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '12 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:02:59

US3312224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:02:59

US3312224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4)	19 Oct 2020 03:02:59
	Karol Moore (b) (4)	
	(b) (4)	

US3312224

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:03:03

US3312224

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'I'	System	19 Oct 2020 03:03:03

US3312224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:50:45

US3312224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:50:45

US3312224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[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 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:50:45

US3312224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'VISIT3'	System	20 Oct 2020 20:50:45

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '08:32'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered '19 Oct 2020 08:32'	System	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '59'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'bpm'	System	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'breaths/min'	System	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '128'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'mmHg'	System	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '67'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'mmHg'	System	20 Oct 2020 20:51:17

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03

US3312224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03

US3312224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:52:09
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 20:51:34

US3312224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '19 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:52:09
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:51:34

US3312224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:55

US3312224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:55

US3312224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered '09:21'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:51:55

US3312224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered '19 Oct 2020 09:21'	System	20 Oct 2020 20:51:55

US3312224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:12:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:52:22

US3312224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'I'	System	20 Oct 2020 20:52:22

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 64'	System	24 Aug 2020 15:08:55

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-26T16:31:44', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '067588c5-9280-4971-9ffd-139dda86f3be'	System	26 Oct 2020 21:32:00
User entered 'No (N)'	System	26 Oct 2020 21:32:00

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-26T16:31:51', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '067588c5-9280-4971-9ffd-139dda86f3be'	System	26 Oct 2020 21:32:00
User entered 'No (N)'	System	26 Oct 2020 21:32:00

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-10-26T16:31:59', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '067588c5-9280-4971-9ffd-139dda86f3be' User entered '26 Oct 2020 16:31:59'	System	26 Oct 2020 21:32:00
	System	26 Oct 2020 21:32:00

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 15:08:55

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 71'	System	24 Aug 2020 15:08:55

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-11-02T15:30:51', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '62179d28-bac6-4456-b376-960591f56156' User entered 'No (N)'	System	02 Nov 2020 21:31:11
	System	02 Nov 2020 21:31:11

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-11-02T15:30:58', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '62179d28-bac6-4456-b376-960591f56156'	System	02 Nov 2020 21:31:11
User entered 'No (N)'	System	02 Nov 2020 21:31:11

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-11-02T15:31:08', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '62179d28-bac6-4456-b376-960591f56156' User entered '02 Nov 2020 15:31:08'	System	02 Nov 2020 21:31:11
	System	02 Nov 2020 21:31:11

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 15:08:55

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered 'Day 78'	System	24 Aug 2020 15:08:55

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-11-09T16:16:22', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd31a03c0-7f44-4236-9438-007518d4debf' User entered 'No (N)'	System	09 Nov 2020 22:17:22
	System	09 Nov 2020 22:17:22

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-11-09T16:16:27', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd31a03c0-7f44-4236-9438-007518d4debf'	System	09 Nov 2020 22:17:22
User entered 'Yes (Y)'	System	09 Nov 2020 22:17:22

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Please 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 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-11-09T16:16:44', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd31a03c0-7f44-4236-9438-007518d4debf' User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 22:17:22

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-11-09T16:17:12', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd31a03c0-7f44-4236-9438-007518d4debf' User entered '09 Nov 2020 16:17:12'	System	09 Nov 2020 22:17:22
	System	09 Nov 2020 22:17:22

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 15:08:55

US3312224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:19:23
Data entry locked.	System	24 Aug 2020 15:08:55
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 15:08:55

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-06T17:52:42', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a241839a-a803-47a3-8aeb-3f64dcc9607d' User entered 'No (N)'	System	06 Dec 2020 23:53:17
	System	06 Dec 2020 23:53:17

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-06T17:52:48', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a241839a-a803-47a3-8aeb-3f64dcc9607d' User entered 'Yes (Y)'	System	06 Dec 2020 23:53:17
	System	06 Dec 2020 23:53:17

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Please 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-06T17:52:58', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a241839a-a803-47a3-8aeb-3f64dcc9607d'	System	06 Dec 2020 23:53:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 23:53:17

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-06T17:53:09', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a241839a-a803-47a3-8aeb-3f64dcc9607d' User entered '06 Dec 2020 17:53:09'	System	06 Dec 2020 23:53:17
	System	06 Dec 2020 23:53:17

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-17T15:30:46', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b4784787-62ac-4c2d-a440-7e539c719b2b'	System	17 Dec 2020 21:31:31
User entered 'No (N)'	System	17 Dec 2020 21:31:31

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-17T15:30:52', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b4784787-62ac-4c2d-a440-7e539c719b2b'	System	17 Dec 2020 21:31:31
User entered 'Yes (Y)'	System	17 Dec 2020 21:31:31

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Please 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-17T15:31:04', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b4784787-62ac-4c2d-a440-7e539c719b2b'	System	17 Dec 2020 21:31:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 21:31:31

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-17T15:31:22', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'b4784787-62ac-4c2d-a440-7e539c719b2b' User entered '17 Dec 2020 15:31:22'	System	17 Dec 2020 21:31:31
	System	17 Dec 2020 21:31:31

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-23T16:23:37', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '627fb874-031b-4fa7-a136-8131910f5e04'	System	23 Dec 2020 22:23:54
User entered 'No (N)'	System	23 Dec 2020 22:23:54

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-23T16:23:45', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '627fb874-031b-4fa7-a136-8131910f5e04'	System	23 Dec 2020 22:23:54
User entered 'No (N)'	System	23 Dec 2020 22:23:54

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2020-12-23T16:23:50', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '627fb874-031b-4fa7-a136-8131910f5e04' User entered '23 Dec 2020 16:23:50'	System	23 Dec 2020 22:23:54
	System	23 Dec 2020 22:23:54

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-01-13T11:39:48', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '339b4de5-17f7-47a1-bf96-ad5d1dd0fd81' User entered 'No (N)'	System	13 Jan 2021 17:40:06
	System	13 Jan 2021 17:40:06

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-01-13T11:39:53', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '339b4de5-17f7-47a1-bf96-ad5d1dd0fd81' User entered 'No (N)'	System	13 Jan 2021 17:40:06
	System	13 Jan 2021 17:40:06

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-01-13T11:40:02', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '339b4de5-17f7-47a1-bf96-ad5d1dd0fd81' User entered '13 Jan 2021 11:40:02'	System	13 Jan 2021 17:40:06
	System	13 Jan 2021 17:40:06

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-01-20T14:23:14', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '326670a2-f8f3-4eaa-bf71-887affd276c3' User entered 'No (N)'	System	20 Jan 2021 20:23:29

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-01-20T14:23:19', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '326670a2-f8f3-4eaa-bf71-887affd276c3'	System	20 Jan 2021 20:23:29
User entered 'No (N)'	System	20 Jan 2021 20:23:29

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-01-20T14:23:25', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '326670a2-f8f3-4eaa-bf71-887affd276c3'	System	20 Jan 2021 20:23:29
User entered '20 Jan 2021 14:23:25'	System	20 Jan 2021 20:23:29

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-01-28T11:54:05', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e28d395f-ab35-4b90-8185-24fe8b52417e' User entered 'No (N)'	System	28 Jan 2021 17:54:38
	System	28 Jan 2021 17:54:38

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-01-28T11:54:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e28d395f-ab35-4b90-8185-24fe8b52417e' User entered 'No (N)'	System	28 Jan 2021 17:54:38
	System	28 Jan 2021 17:54:38

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-01-28T11:54:31', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e28d395f-ab35-4b90-8185-24fe8b52417e' User entered '28 Jan 2021 11:54:31'	System	28 Jan 2021 17:54:38
	System	28 Jan 2021 17:54:38

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-02-12T08:31:02', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '37c40dde-2761-4c16-9f84-f966120dcb48' User entered 'No (N)'	System	12 Feb 2021 14:31:16
	System	12 Feb 2021 14:31:16

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-02-12T08:31:07', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '37c40dde-2761-4c16-9f84-f966120dcb48' User entered 'No (N)'	System	12 Feb 2021 14:31:16
	System	12 Feb 2021 14:31:16

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-02-12T08:31:13', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '37c40dde-2761-4c16-9f84-f966120dcb48' User entered '12 Feb 2021 08:31:13'	System	12 Feb 2021 14:31:16
	System	12 Feb 2021 14:31:16

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-04T11:57:49-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '85b9b27d-9468-4c8a-8e06-0891b8427f87'	System	04 Mar 2021 18:00:34
User entered 'Yes (Y)'	System	04 Mar 2021 18:00:34

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-04T11:57:57-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '85b9b27d-9468-4c8a-8e06-0891b8427f87'	System	04 Mar 2021 18:00:34
User entered 'No (N)'	System	04 Mar 2021 18:00:34

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-04T11:59:46-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '85b9b27d-9468-4c8a-8e06-0891b8427f87'	System	04 Mar 2021 18:00:34
User entered 'No (N)'	System	04 Mar 2021 18:00:34

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-04T11:59:55-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '85b9b27d-9468-4c8a-8e06-0891b8427f87'	System	04 Mar 2021 18:00:34
User entered 'Yes (Y)'	System	04 Mar 2021 18:00:34

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Please 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-04T12:00:06-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '85b9b27d-9468-4c8a-8e06-0891b8427f87'	System	04 Mar 2021 18:00:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Mar 2021 18:00:34

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-04T12:00:13-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '85b9b27d-9468-4c8a-8e06-0891b8427f87'	System	04 Mar 2021 18:00:34
User entered '04 Mar 2021 12:00:13'	System	04 Mar 2021 18:00:34

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-11T17:14:54-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e103b7d3-7f31-4fac-baa0-c954952b8727'	System	11 Mar 2021 23:17:41
User entered 'No (N)'	System	11 Mar 2021 23:17:41

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-11T17:15:01-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e103b7d3-7f31-4fac-baa0-c954952b8727'	System	11 Mar 2021 23:17:41
User entered 'No (N)'	System	11 Mar 2021 23:17:41

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-11T17:15:08-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e103b7d3-7f31-4fac-baa0-c954952b8727'	System	11 Mar 2021 23:17:41
User entered '11 Mar 2021 17:15:08'	System	11 Mar 2021 23:17:41

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-25T17:37:11-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd23375d3-1c54-48ed-ab9a-bc6dd5640ea9'	System	25 Mar 2021 22:38:29
User entered 'No (N)'	System	25 Mar 2021 22:38:29

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-25T17:37:16-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd23375d3-1c54-48ed-ab9a-bc6dd5640ea9'	System	25 Mar 2021 22:38:29
User entered 'No (N)'	System	25 Mar 2021 22:38:29

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-25T17:37:21-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd23375d3-1c54-48ed-ab9a-bc6dd5640ea9'	System	25 Mar 2021 22:38:29
User entered '25 Mar 2021 17:37:21'	System	25 Mar 2021 22:38:29

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-02T15:46:42-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e5bdb9c2-2124-4141-8391-cc00eb4a9b15'	System	02 Apr 2021 20:46:54
User entered 'No (N)'	System	02 Apr 2021 20:46:54

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-02T15:46:47-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e5bdb9c2-2124-4141-8391-cc00eb4a9b15'	System	02 Apr 2021 20:46:54
User entered 'No (N)'	System	02 Apr 2021 20:46:54

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-02T15:46:51-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'e5bdb9c2-2124-4141-8391-cc00eb4a9b15'	System	02 Apr 2021 20:46:54
User entered '02 Apr 2021 15:46:51'	System	02 Apr 2021 20:46:54

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-08T16:30:01-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd89352e7-e8a6-45c4-9b34-556173d9459b'	System	08 Apr 2021 21:30:17
User entered 'No (N)'	System	08 Apr 2021 21:30:17

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-08T16:30:06-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd89352e7-e8a6-45c4-9b34-556173d9459b'	System	08 Apr 2021 21:30:17
User entered 'No (N)'	System	08 Apr 2021 21:30:17

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-08T16:30:14-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'd89352e7-e8a6-45c4-9b34-556173d9459b'	System	08 Apr 2021 21:30:17
User entered '08 Apr 2021 16:30:14'	System	08 Apr 2021 21:30:17

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-14T19:05:09-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '50ba0ab6-2d59-449c-8f88-ed2e21507096'	System	15 Apr 2021 00:05:21
User entered 'No (N)'	System	15 Apr 2021 00:05:21

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-14T19:05:12-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '50ba0ab6-2d59-449c-8f88-ed2e21507096'	System	15 Apr 2021 00:05:21
User entered 'No (N)'	System	15 Apr 2021 00:05:21

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-14T19:05:16-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '50ba0ab6-2d59-449c-8f88-ed2e21507096'	System	15 Apr 2021 00:05:21
User entered '14 Apr 2021 19:05:16'	System	15 Apr 2021 00:05:21

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-22T15:10:54-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a3e7f298-61fb-453f-94a1-8a35d7884c9b'	System	22 Apr 2021 20:11:30
User entered 'No (N)'	System	22 Apr 2021 20:11:30

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-22T15:11:19-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a3e7f298-61fb-453f-94a1-8a35d7884c9b'	System	22 Apr 2021 20:11:30
User entered 'No (N)'	System	22 Apr 2021 20:11:30

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-22T15:11:26-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'a3e7f298-61fb-453f-94a1-8a35d7884c9b'	System	22 Apr 2021 20:11:30
User entered '22 Apr 2021 15:11:26'	System	22 Apr 2021 20:11:30

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-29T17:30:29-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c8305cca-9b60-429b-b1c3-e3283a98d917'	System	29 Apr 2021 22:30:47
User entered 'No (N)'	System	29 Apr 2021 22:30:47

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

Have you been exposed to someone with 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 (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-29T17:30:32-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c8305cca-9b60-429b-b1c3-e3283a98d917'	System	29 Apr 2021 22:30:47
User entered 'No (N)'	System	29 Apr 2021 22:30:47

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-04-29T17:30:36-05:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: 'c8305cca-9b60-429b-b1c3-e3283a98d917'	System	29 Apr 2021 22:30:47
User entered '29 Apr 2021 17:30:36'	System	29 Apr 2021 22:30:47

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:35:22

US3312224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:35:22
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:35:22

US3312224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:03:13

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 12:17:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-04T12:00:25-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '154c9a03-d893-4ad9-a59c-988e5c4af11c'	System	04 Mar 2021 18:01:42
User entered 'No (N)'	System	04 Mar 2021 18:01:42

US3312224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:03:13

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:17:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DA64ECBC-5BF9-4EE0-8B2B-6733A5A8F42B)', Time: '2021-03-04T12:00:33-06:00', User OID: 'PatientReportedOutcome (US3312224)', ODM File OID: '154c9a03-d893-4ad9-a59c-988e5c4af11c' User entered '04 Mar 2021 12:00:33'	System	04 Mar 2021 18:01:42
	System	04 Mar 2021 18:01:42

US3312224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:48:17

US3312224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:48:17

US3312224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:48:17

US3312224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:48:17

US3312224

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:48:41

US3312224

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:03
User entered 'I'	System	17 Nov 2020 15:48:41

US3312224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Dec 2020 19:17:19

US3312224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '18 Dec 2020'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Dec 2020 19:17:19

US3312224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Dec 2020 19:17:19

US3312224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Dec 2020 19:17:19

US3312224

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	18 Dec 2020 19:17:25

US3312224

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User entered 'I'	System	18 Dec 2020 19:17:25

US3312224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:33:59

US3312224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:33:59

US3312224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:33:59

US3312224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:33:59

US3312224

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:34:04

US3312224

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User entered 'I'	System	03 Feb 2021 15:34:04

US3312224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:22:37

US3312224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:22:37

US3312224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:22:37

US3312224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:22:37

US3312224

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:22:40

US3312224

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:29:46
User entered 'I'	System	17 Feb 2021 15:22:40

US3312224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	14 Apr 2021 15:48:13
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered '01 Apr 2021'	Monica Atwood (b) (4)	14 Apr 2021 15:48:13
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered 'Clinic (Clinic)'	Monica Atwood (b) (4)	14 Apr 2021 15:48:13
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	14 Apr 2021 15:48:13

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4)	14 Apr 2021 15:48:58
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	14 Apr 2021 15:48:44
User entered 'No (N)'	Monica Atwood (b) (4)	14 Apr 2021 15:48:44
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty; reason for change Data Entry Error	Monica Atwood (b) (4)	14 Apr 2021 15:48:58
	(b) (4)	
User entered '01 Apr 2021'	Monica Atwood (b) (4)	14 Apr 2021 15:48:44
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:48:44
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:48:44

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:48:44
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:48:44
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:48:44
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:48:44
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:48:44

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:48:44
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:48:44

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:48:44
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:48:44

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:48:44
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:48:44

US3312224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	14 Apr 2021 15:49:14
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered '01 Apr 2021'	Monica Atwood (b) (4)	14 Apr 2021 15:49:14
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	14 Apr 2021 15:49:33
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered '01 Apr 2021'	Monica Atwood (b) (4)	14 Apr 2021 15:49:33
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered '12:14'	Monica Atwood (b) (4)	14 Apr 2021 15:49:33
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 12:14'	System	14 Apr 2021 15:49:33

US3312224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	14 Apr 2021 15:49:39
	(b) (4)	

US3312224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 15:49:39

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	Monica Atwood (b) (4)	25 Jan 2021 18:46:58

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '21 Jan 2021'	Monica Atwood (b) (4)	25 Jan 2021 18:46:58

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Clinic (Clinic)'	Monica Atwood (b) (4)	25 Jan 2021 18:46:58

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 18:46:58

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '21 Jan 2021'	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:46:06

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	Monica Atwood (b) (4)	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
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 13:46:06

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '21 Jan 2021'	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Placebo (Placebo)'	Monica Atwood (b) (4)	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Placebo (Placebo)'	Monica Atwood (b) (4)	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Placebo (Placebo)'	Monica Atwood (b) (4)	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	Monica Atwood (b) (4)	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered '1'	System	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:13

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'I'	System	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered missing code ND - Not Done.	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered missing code ND - Not Done.	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered empty.	System	25 Jan 2021 18:49:57
DataPoint set to visible.	System	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered missing code ND - Not Done.	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered missing code ND - Not Done.	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered empty.	System	25 Jan 2021 18:49:57
DataPoint set to visible.	System	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User accepted default value 'Pre-Dose (PREDOSE)'	Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '21 Jan 2021'	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '12:20'	Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered '21 Jan 2021 12:20'	System	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '98.0' F	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Oral (Oral)'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '62'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'bpm'	System	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '16'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'breaths/min'	System	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '140'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'mmHg'	System	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '73'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'mmHg'	System	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered missing code ND - Not Done.	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered missing code ND - Not Done.	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:49:57

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered empty.	System	25 Jan 2021 18:49:57
DataPoint set to visible.	System	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User accepted default value 'Post-Dose (POSTDOSE)'	Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	Monica Atwood (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '21 Jan 2021'	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '13:55'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered '21 Jan 2021 13:55'	System	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '97.7' F	Monica Atwood (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Oral (Oral)'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '63'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'bpm'	System	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '14'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'breaths/min'	System	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '132'	Monica Atwood (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'mmHg'	System	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '74'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'mmHg'	System	25 Jan 2021 18:51:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	Monica Atwood (b) (4)	25 Jan 2021 18:51:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '21 Jan 2021'	Monica Atwood (b) (4)	25 Jan 2021 18:51:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	Monica Atwood (b) (4)	25 Jan 2021 18:52:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) Monica Atwood (b) (4)	25 Jan 2021 18:52:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	Monica Atwood (b) (4)	25 Jan 2021 18:52:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'mRNA-1273'	System	25 Jan 2021 18:52:01
DataPoint set to visible.	System	25 Jan 2021 18:47:30

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '21 Jan 2021'	Monica Atwood (b) (4)	25 Jan 2021 18:52:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '13:24'	Monica Atwood (b) (4)	25 Jan 2021 18:52:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered '21 Jan 2021 13:24'	System	25 Jan 2021 18:52:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Left Arm (LEFT ARM)'	Monica Atwood (b) (4)	25 Jan 2021 18:52:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'ONCE'	System	25 Jan 2021 18:52:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 18:52:01

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	Monica Atwood (b) (4)	25 Jan 2021 18:48:16

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '21 Jan 2021'	Monica Atwood (b) (4)	25 Jan 2021 18:48:16

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '12:11'	Monica Atwood (b) (4)	25 Jan 2021 18:48:16

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered '21 Jan 2021 12:11'	System	25 Jan 2021 18:48:16

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	Monica Atwood (b) (4)	25 Jan 2021 18:48:33

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:03:13

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '21 Jan 2021'	Monica Atwood (b) (4)	25 Jan 2021 18:48:33

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:03:13

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '12:10'	(b) (4) Monica Atwood (b) (4) (b) (4)	25 Jan 2021 18:48:33

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:03:13

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered '21 Jan 2021 12:10'	System	25 Jan 2021 18:48:33

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	Monica Atwood (b) (4)	25 Jan 2021 18:48:38

US3312224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:17:35
User entered 'I'	System	25 Jan 2021 18:48:38

US3312224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 15:35:04

US3312224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered '29 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 15:35:04

US3312224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Feb 2021 15:35:04

US3312224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 15:35:04

US3312224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 15:35:08

US3312224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User entered 'I'	System	03 Feb 2021 15:35:08

US3312224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User entered 'I'	System	03 Feb 2021 15:35:08
DataPoint set to visible.	System	03 Feb 2021 15:35:08

US3312224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:44

US3312224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:44

US3312224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:41:44

US3312224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'OLD29'	System	26 Feb 2021 20:41:44

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '10:14'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered '18 Feb 2021 10:14'	System	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '67'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'bpm'	System	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '14'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'breaths/min'	System	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '117'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'mmHg'	System	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '62'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'mmHg'	System	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '12:14'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered '18 Feb 2021 12:14'	System	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '62'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'bpm'	System	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '14'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'breaths/min'	System	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '113'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'mmHg'	System	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '63'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'mmHg'	System	26 Feb 2021 20:45:25

US3312224

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:36

US3312224

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:36

US3312224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:53

US3312224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:53

US3312224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:53

US3312224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'mRNA-1273'	System	26 Feb 2021 20:45:53
DataPoint set to visible.	System	03 Feb 2021 15:35:08

US3312224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:53

US3312224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '11:43'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:53

US3312224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered '18 Feb 2021 11:43'	System	26 Feb 2021 20:45:53

US3312224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:45:53

US3312224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'ONCE'	System	26 Feb 2021 20:45:53

US3312224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 20:45:53

US3312224

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:46:04

US3312224

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:53
User entered 'I'	System	26 Feb 2021 20:46:04

US3312224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:49:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:46:36

US3312224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:49:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:46:36

US3312224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:49:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:46:36

US3312224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:49:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:46:36

US3312224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:49:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 20:46:42

US3312224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:49:28
User entered 'I'	System	26 Feb 2021 20:46:42

US3312224

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	14 Apr 2021 15:50:01
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered '01 Apr 2021'	Monica Atwood (b) (4)	14 Apr 2021 15:50:01
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered 'Clinic (Clinic)'	Monica Atwood (b) (4)	14 Apr 2021 15:50:01
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:13

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	14 Apr 2021 15:50:01

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered 'No (N)'	Monica Atwood (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:50:06

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:50:06

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:50:06

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:50:06

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 15:50:06

US3312224

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	14 Apr 2021 15:50:15
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered '01 Apr 2021'	Monica Atwood (b) (4)	14 Apr 2021 15:50:15
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	14 Apr 2021 15:50:26
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered '01 Apr 2021'	Monica Atwood (b) (4)	14 Apr 2021 15:50:26
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
User entered '12:14'	Monica Atwood (b) (4)	14 Apr 2021 15:50:26
	(b) (4)	

US3312224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 12:14'	System	14 Apr 2021 15:50:26

US3312224

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:03:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:52
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:05:45
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:52:06
User entered 'Yes (Y)'	(b) (4)	19 Oct 2020 03:03:17
	Karol Moore (b) (4)	
	(b) (4)	

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site haemorrhage, LLT: Ecchymosis injection site - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 05:07:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 05:07:53
Data point term sent to Coder	System	19 Oct 2020 03:04:30
User entered 'ecchymosis AT INJECTION SITE'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
User closed query 'Per CDM: SAR = No. However, this event is recorded in eDiary 2 and is a solicited event per protocol. Please review and update. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 08:19:07
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:51:40
Query 'Per CDM: SAR = No. However, this event is recorded in eDiary 2 and is a solicited event per protocol. Please review and update. ' answered with 'ECCHYMOSIS IS A SOLICITED ADVERSE REACTION' (Site from DM).	Karol Moore (b) (4) (b) (4)	26 Apr 2021 15:56:23
User opened query 'Per CDM: SAR = No. However, this event is recorded in eDiary 2 and is a solicited event per protocol. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 18:57:50
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 03:04:41
User entered '10:08' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:41
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 03:04:22
User entered empty.	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User entered '21 Sep 2020 10:08'	System	19 Oct 2020 03:04:41
User entered empty.	System	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	19 Oct 2020 22:04:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '19 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:04:54
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	19 Oct 2020 03:04:53
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	19 Oct 2020 03:04:53
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	19 Oct 2020 03:04:22
User entered empty.	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'Per CDM-Response provided for end time is recorded as 'UNKNOWN'. Per CCG page 22, kindly consider to update the response unknown in the field 'end time '. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:08:11
Query 'Per CDM-Response provided for end time is recorded as 'UNKNOWN'. Per CCG page 22, kindly consider to update the response unknown in the field 'end time '. Thank you.' answered with 'Please clarify query. time cannot be entered as unknown. End time is unknown. ' (Site from DM).	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:54:08
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Oct 2020 23:47:52
User entered empty; reason for change Data Entry Error	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:47:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Oct 2020 23:47:36
User entered 'un:un' (non-conformant).	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:47:36
User opened query 'Per CDM-Response provided for end time is recorded as 'UNKNOWN'. Per CCG page 22, kindly consider to update the response unknown in the field 'end time '. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:19:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 08:19:07
Query 'Data is required. Please provide.' answered with 'UNKNOWN' (Site from System).	Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:05:01
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 22:04:54
User entered empty.	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User entered empty.	System	22 Oct 2020 23:47:52
User entered '19 Oct 2020 UN:UN' (non-conformant).	System	22 Oct 2020 23:47:36
User entered empty.	System	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Related (RELATED)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'None (NONE)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Oct 2020 03:04:59
User entered '1' reason for change: Data Entry Error	Karol Moore (b) (4)	19 Oct 2020 03:04:59
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	19 Oct 2020 03:04:22
User entered '0'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:04:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Karol Moore (b) (4) (b) (4)	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User entered '0'	System	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00
User entered '0'	System	19 Oct 2020 03:04:22

US3312224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:00

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:16:57
User entered	System	23 Feb 2021 14:16:53
'USA-US300-2021-mRNA-1273-P301000018'		
User entered 'New'	(b) (4), (b) (6)	23 Feb 2021 14:16:53

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Haemorrhage intracranial, LLT: Intracranial hemorrhage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 00:32:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 00:32:48
Data point term sent to Coder	System	23 Feb 2021 00:23:58
User entered 'INTRAcrANIAL HEMMORRHAGE'	(b) (4), (b) (6)	23 Feb 2021 00:23:41
reason for change: Data Entry Error		
Data point term sent to Coder	System	23 Feb 2021 00:22:58
User entered 'intercranial hemmorrhage'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '19 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'Per CDM: Please consider to provide start time.Thank you' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:52:34
Query 'Per CDM: Please consider to provide start time.Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:35:52
User entered '01:00' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:35:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 06:26:57
User opened query 'Per CDM: Please consider to provide start time.Thank you' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:26:55
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 23:41:45
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Feb 2021 20:45:53
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Feb 2021 01:00'	System	08 Apr 2021 17:35:38
User entered empty.	System	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)' reason for change: New Information	Heather Barker (b) (4) (b) (4)	02 Apr 2021 12:25:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '18 Mar 2021' reason for change: New Information	Heather Barker (b) (4) (b) (4)	02 Apr 2021 12:25:58
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'Per CDM: Please consider to provide End time. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:52:46
Query 'Per CDM: Please consider to provide End time. Thank you' answered with 'NA' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:35:46
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 06:27:21
User opened query 'Per CDM: Please consider to provide End time. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:27:17
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 23:40:12
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Apr 2021 12:25:58
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
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)	23 Feb 2021 09:50:46
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 'currently still hospitablzed' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 00:23:14
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	23 Feb 2021 00:22:36
User entered 'I'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '19 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'PV Query: The hospital discharge date was reported as 24 Feb 2021 for thrombocytopenia and 25 Feb 2021 for intracranial hemorrhage. Please confirm and provide the hospital discharge date for both events.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:31:51
Query 'PV Query: The hospital discharge date was reported as 24 Feb 2021 for thrombocytopenia and 25 Feb 2021 for intracranial hemorrhage. Please confirm and provide the hospital discharge date for both events.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 23:43:03
User opened query 'PV Query: The hospital discharge date was reported as 24 Feb 2021 for thrombocytopenia and 25 Feb 2021 for intracranial hemorrhage. Please confirm and provide the hospital discharge date for both events.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 21:52:55
User entered '25 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 22:00:45
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 18:29:45
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '4' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 18:29:45
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

None

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:27:54
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' answered with 'no specific treatment for this AE other than hospitalization and observation- no CM or procedures to report. correct as entered' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 23:45:38
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:41:53
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 23:22:58
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Feb 2021 00:22:53
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Feb 2021 00:22:36
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:13:01
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:23:06
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 23:22:58
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 16:44:21
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 00:22:53
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Heather Barker (b) (4) (b) (4)	02 Apr 2021 12:25:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
User closed query 'PV Query: Thank you for providing a hospital discharge summary to PVG ; however, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 16:11:56
Query 'PV Query: Thank you for providing a hospital discharge summary to PVG ; however, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or ' answered with 'SUBMITTED 26APR21' (Site from Safety).	Karol Moore (b) (4) (b) (4)	26 Apr 2021 21:23:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:51:40
User opened query 'PV Query: Thank you for providing a hospital discharge summary to PVG ; however, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 14:12:31
User closed query 'Per DM CLR: Narrative = BRUISING AT INJECTION SITE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:27:44
Query 'Per DM CLR: Narrative = BRUISING AT INJECTION SITE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'see AE #1 Ecchymosis=bruising ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 23:44:45
User opened query 'Per DM CLR: Narrative = BRUISING AT INJECTION SITE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:42:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Narrative](#)

Audit	User	Time (GMT)
User entered '84YO HISTORY OF HTN, CAD, HYPOTHYROIDISM AND CONSTIPATION RECEIVED 1ST VACCINATION OL V1 21JAN2021 AND DEVELOPED MODERATE ABDOMINAL PAIN WITH MINIMAL IMPACT ON ADLS WHICH RESOLVED 10FEB2021 AND BRUISING AT INJECTION SITE. AT OL V2: ABD PAIN AND BRUISING WERE DISCUSSED WITH PT AND THOUGHT TO BE DUE TO CONSTIPATION AND ASA USE RESPECTIVELY, AS BOTH CONSTIPATION AND EASY BRUISING (STATED BY PT TO BE DUE TO ASA AND PREVIOUSLY DISCUSSED WITH PCP AND CARDIOLOGIST) HAVE BEEN PRESENT CHRONICALLY. (ABD PAIN POST NOT MAAE, SO NOT RECORDED IN EDC) ON 02/19/21 SUBJECT FELL AND HIT HIS HEAD, TAKEN TO ER. SUFFERED SUBARACHNOID AND SUBDURAL INTRACRANIAL BLEEDS AND FOUND TO HAVE PLATELETS OF 37. WAS INITIALLY HYPOTENSIVE REQUIRING PRESSOR SUPPORT BUT AT TIME OF CALL-NO LONGER NECESSARY AND SUBJECT WAS STABLE. WILL PROCURE MEDICAL RECORDS. 23MAR2021: SEE FOLLOW UP NARRATIVE SENT TO SAFETY TEAM DUE TO NOT ENOUGH CHARACTERS ALLOWED. 02APR21: See f/u narrative sent to safety team due to not enough characters allowed.' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	02 Apr 2021 12:25:58

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Narrative](#)

Audit	User	Time (GMT)
User entered '84YO HISTORY OF HTN, CAD, HYPOTHYROIDISM AND CONSTIPATION RECEIVED 1ST VACCINATION OL V1 21JAN2021 AND DEVELOPED MODERATE ABDOMINAL PAIN WITH MINIMAL IMPACE ON ADLS WHICH RESOLVED 10FEB2021 AND BRUISING AT INJECTION SITE. AT OL V2: ABD PAIN AND BRUISING WERE DISCUSSED WITH PT AND THOUGH TO BE DUE TO CONSTIPATION AND ASA USE RESPECTIVELY, AS BOTH CONSTIPATION AND EASY BRUISING (STATED BY PT TO BE DUE TO ASA AND PREVIOUSLY DISCUSSED WITH PCP AND CARDIOLOGIST) HAVE BEEN PRESENT CHRONICALLY. (ABD PAIN POST NOT MAAE, SO NOT RECORDED IN EDC) ON 02/19/21 SUBJECT FELL AND HIT HIS HEAD, TAKEN TO ER. SUFFERED SUBARACHNOID AND SUBDURAL INTRACRANIAL BLEEDS AND FOUND TO HAVE PLATELETS OF 37. WAS INITIALLY HYPOTENSIVE REQUIRING PRESSOR SUPPORT BUT AT TIME OF CALL-NO LONGER NECESSARY AND SUBJECT WAS STABLE. WILL PROCURE MEDICAL RECORDS. 23Mar2021: see follow up narrative sent to safety team due to not enough characters allowed' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 22:02:24

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Narrative](#)

Audit	User	Time (GMT)
User entered '84yo history of HTN, CAD, hypothyroidism and constipation received 1st vaccination OL V1 21Jan2021 and developed moderate abdominal pain with minimal impace on ADLs which resolved 10feb2021 and bruising at injection site. At OL v2: abd pain and bruising were discussed with pt and though to be due to constipation and ASA use respectively, as both constipation and easy bruising (stated by pt to be due to ASA and Previously discussed with PCP and cardiologist) have been present chronically. (ABD pain post not MAAE, so not recorded in EDC) On 02/19/21 subject fell and hit his head, taken to ER. Suffered subarachnoid and subdural intracranial bleeds and found to have platelets of 37. Was initially hypotensive requiring pressor support but at time of call-no longer necessary and subject was stable. Will procure medical records.'	(b) (4), (b) (6)	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 00:22:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 00:22:36

US3312224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 18:29:45
User entered '0'	System	23 Feb 2021 00:22:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:17:26
User entered 'USA-US300-2021-mRNA-1273-P301000018'	(b) (4), (b) (6)	23 Feb 2021 14:17:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Leukaemias, HLT: Myelodysplastic syndromes, PT: Myelodysplastic syndrome, LLT: Myelodysplastic syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Apr 2021 12:23:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Apr 2021 12:23:39
Data point term sent to Coder	System	02 Apr 2021 12:22:46
Coding entries removed.	Heather Barker (b) (4) (b) (4)	02 Apr 2021 12:21:55
User entered 'myelodysplastic syndrome' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 12:21:55
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytopenias, PT: Thrombocytopenia, LLT: Thrombocytopenia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 00:26:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 00:26:54
Data point term sent to Coder	System	23 Feb 2021 00:25:59
User entered 'thrombocytopenia'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:03:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '19 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Mar 2021 18:28:50
User entered '01:00' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 18:28:50
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Feb 2021 20:45:53
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Feb 2021 01:00'	System	25 Mar 2021 18:28:50
User entered empty.	System	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
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) (4), (b) (6)	30 Apr 2021 13:10:09
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 'ongoing' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:30:52
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)	27 Apr 2021 22:17:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query '(AE #3, #4) 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)	19 Apr 2021 20:58:42
Query '(AE #3, #4) 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 'still ongoing and in PI opinion will become chronic' (Site from Safety).	Carlos Fierro (b) (4) (b) (4)	16 Apr 2021 20:04:32
User opened query '(AE #3, #4) PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:25:35
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:17:17
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)	26 Apr 2021 14:00:49
User entered empty.	System	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'PV Query: As per additional information provided, event of myelodysplastic syndrome was considered a medically important event, however only hospitalization is selected for seriousness criteria. Please confirm if medically important should also be selected, and if so, please update eCRF. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:55:43
Query 'PV Query: As per additional information provided, event of myelodysplastic syndrome was considered a medically important event, however only hospitalization is selected for seriousness criteria. Please confirm if medically important should also be selected, and if so, please update eCRF. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:53:49
User opened query 'PV Query: As per additional information provided, event of myelodysplastic syndrome was considered a medically important event, however only hospitalization is selected for seriousness criteria. Please confirm if medically important should also be selected, and if so, please update eCRF. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:11:19
User closed query '(AE #3) 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)	26 Mar 2021 18:09:37
Query '(AE #3) 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 'Negative SARS COV2 19Feb2021 per med record' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:21:47
User closed query '(AE #3, #4) PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:09:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:09:33
Query '(AE #3, #4) PV Query: Please provide the hospital discharge date when available. ' answered with 'Updated: sent to Safety team 3/23/21' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 22:05:56
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'updated: sent to safety team 3/23/21' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 22:04:20
User opened query '(AE #3) 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)	01 Mar 2021 16:28:12
User opened query '(AE #3, #4) PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:27:46
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:27:34
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)	23 Feb 2021 10:01:33

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EAB) (1725)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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 'currently hospitalized ' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 00:25:31
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	23 Feb 2021 00:25:00
User entered '1'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Generated On: 09 Jun 2021 17:03:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '19 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
User closed query 'PV Query: Thank you for your confirmation of discharge date. Please update EDC with discharge date for both events as well.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 16:12:13
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:51:40
Query 'PV Query: Thank you for your confirmation of discharge date. Please update EDC with discharge date for both events as well.' answered with 'UPDATED BOTH EVENTS' (Site from Safety).	Karol Moore (b) (4) (b) (4)	26 Apr 2021 16:05:51
User opened query 'PV Query: Thank you for your confirmation of discharge date. Please update EDC with discharge date for both events as well.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 14:05:42
User closed query 'PV Query: The hospital discharge date was reported as 24 Feb 2021 for thrombocytopenia and 25 Feb 2021 for intracranial hemorrhage. Please confirm and provide the hospital discharge date for both events.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:58:46
Query 'PV Query: The hospital discharge date was reported as 24 Feb 2021 for thrombocytopenia and 25 Feb 2021 for intracranial hemorrhage. Please confirm and provide the hospital discharge date for both events.' answered with 'discharge date for both is 24Feb21' (Site from Safety).	Carlos Fierro (b) (4) (b) (4)	16 Apr 2021 20:03:24
User opened query 'PV Query: The hospital discharge date was reported as 24 Feb 2021 for thrombocytopenia and 25 Feb 2021 for intracranial hemorrhage. Please confirm and provide the hospital discharge date for both events.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 12:33:56
User closed query 'PV Query: The hospital discharge date was reported as 24 Feb 2021 for myelodysplastic syndrome and 25 Feb 2021 for intracranial hemorrhage. Please confirm and provide the hospital discharge date for both events.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:55:51

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Generated On: 09 Jun 2021 17:03:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: The hospital discharge date was reported as 24 Feb 2021 for myelodysplastic syndrome and 25 Feb 2021 for intracranial hemorrhage. Please confirm and provide the hospital discharge date for both events. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:54:46
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 17:54:18
User opened query 'PV Query: The hospital discharge date was reported as 24 Feb 2021 for myelodysplastic syndrome and 25 Feb 2021 for intracranial hemorrhage. Please confirm and provide the hospital discharge date for both events. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:12:30
User entered '25 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 23:42:41
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 22:03:53
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 18:25:20
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '4' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 18:25:20
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

US3312224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 17:53:12
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query '(AE #3, #4) PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 21 Jan 2021, then event occurred). ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:10:22
Query '(AE #3, #4) PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 21 Jan 2021, then event occurred). ' answered with 'NA-received both doses' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 22:06:37
User opened query '(AE #3, #4) PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 21 Jan 2021, then event occurred). ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:28:00
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query '(AE #3, #4) PV Query: Please provide treatment given (steroids or other) 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)	26 Mar 2021 18:09:42
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 05:00:08
Query '(AE #3, #4) PV Query: Please provide treatment given (steroids or other) for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:28:09
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 16:45:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query '(AE #3, #4) PV Query: Please provide treatment given (steroids or other) for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:26:04
User entered 'I'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
User closed query 'PV Re-Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing/chronic conditions.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 16:12:17
Query 'PV Re-Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing/chronic conditions.' answered with 'PENDING RESOLUTION. CONFIRMED STILL ONGOING.' (Site from Safety).	Karol Moore (b) (4) (b) (4)	26 Apr 2021 20:40:59
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:51:40
Query '(AE #3, #4) PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 14:04:38
User opened query 'PV Re-Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing/chronic conditions.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 14:04:24
User opened query '(AE #3, #4) PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:25:48
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
User closed query 'PV Query: Thank you for providing a hospital discharge summary to PVG ; however, 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 (add protocol and subject ID to cover page).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 16:12:25
User closed query 'PV Query: Please clarify other blood cell abnormalities contributing to diagnosis of myelodysplastic syndrome considering that the event was updated from thrombocytopenia with only low platelet count described.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 16:12:21
Query 'PV Query: Thank you for providing a hospital discharge summary to PVG ; however, 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 (add protocol and subject ID to cover page).' answered with 'SUBMITTED 26APR21' (Site from Safety).	Karol Moore (b) (4) (b) (4)	26 Apr 2021 21:23:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:51:40
Query 'PV Query: Please clarify other blood cell abnormalities contributing to diagnosis of myelodysplastic syndrome considering that the event was updated from thrombocytopenia with only low platelet count described.' answered with '2/24/21 at 0647: WBC 6.43 Hgb 11.3(L) Plts 66(L) 2/21/21 0000: WBC 4.97 Hgb 11.8(L) Plts 54 2/19/21 0832: WBC 3.81 (L) Hgb 9.6(L) Plts 37(L) 92% segs (H) 6% lymphs (L), ie, subject had pancytopenia at presentation. Also, a comment in med records revealed: 5/19/17 Plts 104(L), "2 years prior it was also 102(L)" MDS also diagnosed with bone marrow biopsy, the results of which we do not have but subject stated so on phone call.' (Site from Safety).	Carlos Fierro (b) (4) (b) (4)	26 Apr 2021 19:24:28

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify other blood cell abnormalities contributing to diagnosis of myelodysplastic syndrome considering that the event was updated from thrombocytopenia with only low platelet count described.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 14:07:46
User opened query 'PV Query: Thank you for providing a hospital discharge summary to PVG ; however, 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 (add protocol and subject ID to cover page).' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 14:02:17
User closed query 'PV Query: Please clarify other blood cell abnormalities contributing to diagnosis of myelodysplastic syndrome considering that the event was updated from thrombocytopenia with only low platelet count described.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:59:37
User closed query 'PV Query: Thank you for providing a hospital discharge summary to PVG ; however, 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 (add protocol and subject ID to cover page).' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 20:59:24
Query 'PV Query: Thank you for providing a hospital discharge summary to PVG ; however, 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 (add protocol and subject ID to cover page).' answered with 'will do' (Site from Safety).	Carlos Fierro (b) (4) (b) (4)	16 Apr 2021 20:05:12
Query 'PV Query: Please clarify other blood cell abnormalities contributing to diagnosis of myelodysplastic syndrome considering that the event was updated from thrombocytopenia with only low platelet count described.' answered with '19Feb21: wbc 3.8, hgb 9.6, platelets 37, 24Feb21 wbc 6.43, hgb 11.3, platelets 66 04Apr21 at OL day 57/ pre-OL day 209 visit, subject reported recent bone marrow biopsy date unspecified that confirmed myelodysplastic syndrome diagnosis' (Site from Safety).	Carlos Fierro (b) (4) (b) (4)	16 Apr 2021 20:01:55

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify other blood cell abnormalities contributing to diagnosis of myelodysplastic syndrome considering that the event was updated from thrombocytopenia with only low platelet count described.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 12:34:28
User opened query 'PV Query: Thank you for providing a hospital discharge summary to PVG ; however, 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 (add protocol and subject ID to cover page).' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 12:34:16
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:56:29
User closed query 'PV Query: Please provide blood counts (i.e. WBC, RBC and platelets) after July 2020 when lisinopril was initiated and current platelet count to assess recovery. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:56:17
Query 'PV Query: Please provide blood counts (i.e. WBC, RBC and platelets) after July 2020 when lisinopril was initiated and current platelet count to assess recovery. ' answered with 'NOT ENOUGH CHARACTERS ALLOWED, PER MEDICAL RECORDS: PLT 19MAY2017=104K, 2 YEARS PRIOR IT WAS ALSO 102K ' (Site from Safety).	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:36:19
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Medical records including DC summary sent to PVG 24Mar2021' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:55:32

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Folder: Adverse Events

Form: Adverse Events (3)

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Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:10:38
User opened query 'PV Query: Please provide blood counts (i.e. WBC, RBC and platelets) after July 2020 when lisinopril was initiated and current platelet count to assess recovery. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:09:47

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered '84YO HISTORY OF HTN, CAD, HYPOTHYROIDISM AND CONSTIPATION RECEIVED 1ST VACCINATION OL V1 21JAN2021 AND DEVELOPED MODERATE ABDOMINAL PAIN WITH MINIMAL IMPACT ON ADLS WHICH RESOLVED 10FEB2021 AND BRUISING AT INJECTION SITE. AT OL V2: ABD PAIN AND BRUISING WERE DISCUSSED WITH PT AND THOUGHT TO BE DUE TO CONSTIPATION AND ASA USE RESPECTIVELY, AS BOTH CONSTIPATION AND EASY BRUISING (STATED BY PT TO BE DUE TO ASA AND PREVIOUSLY DISCUSSED WITH PCP AND CARDIOLOGIST) HAVE BEEN PRESENT CHRONICALLY. (ABD PAIN POST NOT MAE, SO NOT RECORDED IN EDC) ON 02/19/21 SUBJECT FELL AND HIT HIS HEAD, TAKEN TO ER. SUFFERED SUBARACHNOID AND SUBDURAL INTRACRANIAL BLEEDS AND FOUND TO HAVE PLATELETS OF 37. WAS INITIALLY HYPOTENSIVE REQUIRING PRESSOR SUPPORT BUT AT TIME OF CALL-NO LONGER NECESSARY AND SUBJECT WAS STABLE. WILL PROCURE MEDICAL RECORDS.3/23/21: SEE UPDATED SAE NARRATIVE SENT TO SAFETY TEAM DUE TO NOT ENOUGH CHARACTERS ALLOWED. 02Apr21:SEE UPDATED SAE NARRATIVE SENT TO SAFETY TEAM DUE TO NOT ENOUGH CHARACTERS ALLOWED.'	Heather Barker (b) (4)	02 Apr 2021 12:27:09
reason for change: Data Entry Error		
User closed query '(AE #3) PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc) ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:09:55
User closed query '(AE #3) PV Query: Please confirm if easy bruising is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If easy bruising is a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:09:54

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Folder: Adverse Events

Form: Adverse Events (3)

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Audit	User	Time (GMT)
User closed query '(AE #3) PV Query: Please assess whether injection site bruising and abdominal pain on 21 Jan 2021 meet the criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:09:52
User closed query '(AE #3) PV Query: Please provide if there were any signs of recent infection after dose 1 of the vaccination. ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:09:49
User closed query '(AE #3) PV Query: Please provide blood counts (i.e. WBC, RBC and platelets) after July 2020 when lisinopril was initiated and current platelet count to assess recovery. ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:09:48
User closed query '(AE #3) PV Query: Please provide any investigations that were performed for this patient to investigate the thrombocytopenia e.g. any immune, infection, lymphoproliferative disorders, other?' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:09:45
Query '(AE #3) PV Query: Please provide any investigations that were performed for this patient to investigate the thrombocytopenia e.g. any immune, infection, lymphoproliferative disorders, other?' answered with 'See narrative and DC summary sent to safety team' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:27:57
Query '(AE #3) PV Query: Please provide blood counts (i.e. WBC, RBC and platelets) after July 2020 when lisinopril was initiated and current platelet count to assess recovery. ' answered with 'Discharge summary sent to safety team' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:27:43
Query '(AE #3) PV Query: Please provide if there were any signs of recent infection after dose 1 of the vaccination. ' answered with 'None' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:27:22
Query '(AE #3) PV Query: Please assess whether injection site bruising and abdominal pain on 21 Jan 2021 meet the criteria for separate AE/SAE reporting. ' answered with 'no- as not MAAE' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:27:13

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Audit	User	Time (GMT)
Query '(AE #3) PV Query: Please confirm if easy bruising is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If easy bruising is a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' answered with 'added to med history' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:25:51
Query '(AE #3) PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc) ' answered with 'orthostatic hypotension-AE added' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 18:25:36
User entered '84YO HISTORY OF HTN, CAD, HYPOTHYROIDISM AND CONSTIPATION RECEIVED 1ST VACCINATION OL V1 21JAN2021 AND DEVELOPED MODERATE ABDOMINAL PAIN WITH MINIMAL IMPACT ON ADLS WHICH RESOLVED 10FEB2021 AND BRUISING AT INJECTION SITE. AT OL V2: ABD PAIN AND BRUISING WERE DISCUSSED WITH PT AND THOUGHT TO BE DUE TO CONSTIPATION AND ASA USE RESPECTIVELY, AS BOTH CONSTIPATION AND EASY BRUISING (STATED BY PT TO BE DUE TO ASA AND PREVIOUSLY DISCUSSED WITH PCP AND CARDIOLOGIST) HAVE BEEN PRESENT CHRONICALLY. (ABD PAIN POST NOT MAAE, SO NOT RECORDED IN EDC) ON 02/19/21 SUBJECT FELL AND HIT HIS HEAD, TAKEN TO ER. SUFFERED SUBARACHNOID AND SUBDURAL INTRACRANIAL BLEEDS AND FOUND TO HAVE PLATELETS OF 37. WAS INITIALLY HYPOTENSIVE REQUIRING PRESSOR SUPPORT BUT AT TIME OF CALL-NO LONGER NECESSARY AND SUBJECT WAS STABLE. WILL PROCURE MEDICAL RECORDS.3/23/21: see updated SAE narrative sent to safety team due to not enough characters allowed.' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 22:03:25
User opened query '(AE #3) PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc) ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:28:25

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Audit	User	Time (GMT)
User opened query '(AE #3) PV Query: Please confirm if easy bruising is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If easy bruising is a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:27:16
User opened query '(AE #3) PV Query: Please assess whether injection site bruising and abdominal pain on 21 Jan 2021 meet the criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:26:58
User opened query '(AE #3) PV Query: Please provide if there were any signs of recent infection after dose 1 of the vaccination. ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:26:40
User opened query '(AE #3) PV Query: Please provide blood counts (i.e. WBC, RBC and platelets) after July 2020 when lisinopril was initiated and current platelet count to assess recovery. ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:26:28
User opened query '(AE #3) PV Query: Please provide any investigations that were performed for this patient to investigate the thrombocytopenia e.g. any immune, infection, lymphoproliferative disorders, other?' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:26:17

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[Narrative](#)

Audit	User	Time (GMT)
User entered '84YO HISTORY OF HTN, CAD, HYPOTHYROIDISM AND CONSTIPATION RECEIVED 1ST VACCINATION OL V1 21JAN2021 AND DEVELOPED MODERATE ABDOMINAL PAIN WITH MINIMAL IMPACT ON ADLS WHICH RESOLVED 10FEB2021 AND BRUISING AT INJECTION SITE. AT OL V2: ABD PAIN AND BRUISING WERE DISCUSSED WITH PT AND THOUGHT TO BE DUE TO CONSTIPATION AND ASA USE RESPECTIVELY, AS BOTH CONSTIPATION AND EASY BRUISING (STATED BY PT TO BE DUE TO ASA AND PREVIOUSLY DISCUSSED WITH PCP AND CARDIOLOGIST) HAVE BEEN PRESENT CHRONICALLY. (ABD PAIN POST NOT MAAE, SO NOT RECORDED IN EDC) ON 02/19/21 SUBJECT FELL AND HIT HIS HEAD, TAKEN TO ER. SUFFERED SUBARACHNOID AND SUBDURAL INTRACRANIAL BLEEDS AND FOUND TO HAVE PLATELETS OF 37. WAS INITIALLY HYPOTENSIVE REQUIRING PRESSOR SUPPORT BUT AT TIME OF CALL-NO LONGER NECESSARY AND SUBJECT WAS STABLE. WILL PROCURE MEDICAL RECORDS.'	(b) (4), (b) (6)	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:03:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 18:25:20
User entered '0'	System	23 Feb 2021 00:25:00

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Laceration of head - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 18:44:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 18:44:39
Data point term sent to Coder	System	09 Apr 2021 18:43:58
User entered 'HEAD LACERATION'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '19 Feb 2021'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 18:43:59
User entered '01:00' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:59
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 18:43:47
User entered empty; reason for change Data Entry Error	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:47
User entered '01:00'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Feb 2021 01:00'	System	09 Apr 2021 18:43:59
User entered empty.	System	09 Apr 2021 18:43:47
User entered '19 Feb 2021 01:00'	System	09 Apr 2021 18:43:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Apr 2021 22:38:16
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Apr 2021 22:38:16
User entered '19 Feb 2021'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	12 Apr 2021 22:38:16
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Apr 2021 22:38:16
User opened query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	09 Apr 2021 18:44:11
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 18:44:11
User entered '01:00' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:44:11
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 18:43:47
User closed query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	09 Apr 2021 18:43:47
User entered empty; reason for change Data Entry Error	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:47
User opened query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	09 Apr 2021 18:43:17
User entered '01:00'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 22:38:16
User entered '19 Feb 2021 01:00'	System	09 Apr 2021 18:44:11
User entered empty.	System	09 Apr 2021 18:43:47
User entered '19 Feb 2021 01:00'	System	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Applicable (NOT APPLICABLE)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'I'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Apr 2021 22:38:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:03:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 18:43:17

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncopal attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 18:46:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 18:46:44
Data point term sent to Coder	System	09 Apr 2021 18:46:01
User entered 'SYNCOPAL EPISODE'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '19 Feb 2021'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '01:00'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User entered '19 Feb 2021 01:00'	System	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '19 Feb 2021'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User closed query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	26 Apr 2021 19:01:41
User entered '01:01' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 19:01:41
User opened query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	09 Apr 2021 18:45:33
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 18:45:33
User entered '01:00' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:33
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 18:45:23
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User entered '19 Feb 2021 01:01'	System	26 Apr 2021 19:01:41
User entered '19 Feb 2021 01:00'	System	09 Apr 2021 18:45:33
User entered empty.	System	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Applicable (NOT APPLICABLE)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'l'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User entered '0'	System	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54
User entered 'I'	System	09 Apr 2021 18:45:23

US3312224

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:03:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:30:54

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Orthostatic hypotension, LLT: Orthostatic hypotension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:16:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:16:41
Data point term sent to Coder	System	09 Apr 2021 18:47:06
User entered 'EXACERBATION OF ORTHOSTATIC HYPOTENSION'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '19 Feb 2021'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '01:00'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User entered '19 Feb 2021 01:00'	System	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '22 Feb 2021'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
User closed query 'Per CDM:Please consider to update the End time.Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 08:19:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:51:40
Query 'Per CDM:Please consider to update the End time.Thank you' answered with 'END TIME UNKNOWN' (Site from DM).	Karol Moore (b) (4) (b) (4)	26 Apr 2021 15:52:37
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 06:24:05
User opened query 'Per CDM:Please consider to update the End time.Thank you' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:24:01
Query 'Per CDM:Please consider to update the Start time.Thank you' canceled (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:21:29
User opened query 'Per CDM:Please consider to update the Start time.Thank you' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:21:19
Query 'Data is required. Please provide.' answered with 'EXACT END TIME UNKNOWN' (Site from System).	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:51
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 18:46:38
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User entered empty.	System	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'No (N)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Related (NOT RELATED)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Not Applicable (NOT APPLICABLE)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered '0'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'l'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 17:27:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:51:40
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User entered '0'	System	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09
User entered 'I'	System	09 Apr 2021 18:46:38

US3312224

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:03:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:31:09

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:03:13

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:05:56
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:13:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:14:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:14:54
Data point term sent to Coder	System	02 Sep 2020 18:14:37
User entered 'acetylsalicylic acid'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'cardiac prophylaxis'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '81'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'un UNK 1980'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Un-verified.	(b) (4)	
	Karol Moore (b) (4)	25 Mar 2021 19:55:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	25 Mar 2021 19:55:13
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Sep 2020 18:14:11
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Un-verified.	(b) (4) Karol Moore (b) (4)	25 Mar 2021 19:55:13
User entered '18 Feb 2021' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	25 Mar 2021 19:55:13
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User entered '1'	System	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User entered '1'	System	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:33
User entered '804 (804)'	System	02 Sep 2020 18:14:11

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CARBONATE;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM PLUS VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:23:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:23:32
Data point term sent to Coder	System	19 Oct 2020 22:12:37
Coding entries removed.	Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:12:22
User entered 'CALCIUM PLUS D3 (CALCIUM/VITAMIN D3)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:12:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM PLUS D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:16:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:16:49
Data point term sent to Coder	System	02 Sep 2020 18:15:38
User entered 'calcium plus d3'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'osteoporosis'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '600/800'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one drug unit has been reported in the unit field. Please update the unit to include both components. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:41:49
Query 'Per DM CLR: Please note this is a combination drug; however, only one drug unit has been reported in the unit field. Please update the unit to include both components. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:12:34
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one drug unit has been reported in the unit field. Please update the unit to include both components. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:09:45
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'un UNK 2015'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:15:05

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:00:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:00:43
Data point term sent to Coder	System	02 Sep 2020 18:16:39
User entered 'docusate sodium'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'mild constipation'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '100'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'un UNK 2019'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:15:46

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:17:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:17:52
Data point term sent to Coder	System	02 Sep 2020 18:16:40
User entered 'simvastatin'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'hyperlipidemia'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '40'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'un UNK 2005'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:16:24

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
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.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:18:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:18:52
Data point term sent to Coder	System	02 Sep 2020 18:17:40
User entered 'levothyroxine'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'hypothyroidism'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '50'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (50 mg) of this medication. Please review unit and update (eg. ug, etc.) as applicable. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:36:36
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (50 mg) of this medication. Please review unit and update (eg. ug, etc.) as applicable. ' answered with 'UPDATED PER SOURCE' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:11:09
User entered 'ug (ug)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Oct 2020 22:10:58
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (50 mg) of this medication. Please review unit and update (eg. ug, etc.) as applicable. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 07:49:18
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'un UNK 2019'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 18:16:55

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:18:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 18:18:53
Data point term sent to Coder	System	02 Sep 2020 18:17:43
User entered 'lisinopril'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'hypertension'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '10'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'un Jul 2020'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered '0'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Un-verified.	(b) (4)	
	Karol Moore (b) (4)	25 Mar 2021 19:55:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	25 Mar 2021 19:55:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Sep 2020 18:17:25
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Un-verified.	(b) (4)	
	Karol Moore (b) (4)	25 Mar 2021 19:55:33
User entered '19 Feb 2021' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 19:55:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered empty.	Karol Moore (b) (4)	02 Sep 2020 18:17:25
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:07:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User entered '1'	System	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User entered '1'	System	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:38
User entered '804 (804)'	System	02 Sep 2020 18:17:25

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: PLATELETS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 11:16:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:16:42
Data point term sent to Coder	System	25 Mar 2021 19:57:10
User entered 'PLATELET TRANSFUSION'	Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'thrombocytopenia'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Other (OTHER)'	Karol Moore (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'UNIT'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	25 Mar 2021 20:04:26
User entered 'other (OTHER)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:04:26
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	25 Mar 2021 19:56:59
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'THREE TIMES'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Intravenous (INTRAVENOUS)'	Karol Moore (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '19 Feb 2021'	(b) (4) Karol Moore (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '24 Mar 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'No (N)'	(b) (4)	25 Mar 2021 19:56:59
	Karol Moore (b) (4)	
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User entered empty.	System	25 Mar 2021 20:04:26
User entered '1'	System	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User entered empty.	System	25 Mar 2021 20:04:26
User entered '1'	System	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:41
User entered empty.	System	25 Mar 2021 20:04:26
User entered '804 (804)'	System	25 Mar 2021 19:56:59

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: MIDODRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 10:04:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:04:14
Data point term sent to Coder	System	25 Mar 2021 19:58:15
User entered 'MIDODRINE'	Karol Moore (b) (4) (b) (4)	25 Mar 2021 19:57:44

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered 'ORTHOSTATIC HYPOTENSION'	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered '10'	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered 'three times daily (TID)'	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered '23 Feb 2021'	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:04:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 20:04:31
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	25 Mar 2021 20:04:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 19:57:44
User entered empty.	Karol Moore (b) (4)	25 Mar 2021 19:57:44
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 19:57:44

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 19:57:44

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 19:57:44

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 11:04:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 11:04:42
Data point term sent to Coder	System	25 Mar 2021 20:04:26
User entered 'PHENYLEPHRINE'	Karol Moore (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'EXACERBATION OF ORTHOSTATIC HYPOTENSION'	Karol Moore (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0.6'	Karol Moore (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 20:38:14
User entered 'ug (ug)'	Karol Moore (b) (4)	25 Mar 2021 20:03:49
	(b) (4)	

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Mcg/ KG' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:38:14
User entered empty.	Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Every minute' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 20:38:14
User entered 'CONTINUOUS'	Karol Moore (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Intravenous (INTRAVENOUS)'	Karol Moore (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '19 Feb 2021'	(b) (4) Karol Moore (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '22 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User entered empty.	System	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User entered empty.	System	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:45
User entered empty.	System	25 Mar 2021 20:03:49

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:03:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Karol Moore (b) (4)	25 Mar 2021 20:04:41
	(b) (4)	
User entered 'No (N)'	Monica Atwood (b) (4)	25 Jan 2021 18:52:41
	(b) (4)	

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:03:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:16
	(b) (4)	
User entered '19 Feb 2021'	Karol Moore (b) (4)	25 Mar 2021 20:05:06
	(b) (4)	

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:03:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:16
	(b) (4)	
User entered 'STAPLES TO HEAD'	Karol Moore (b) (4)	25 Mar 2021 20:05:06
	(b) (4)	

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:16
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 06:14:04
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'AE UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 18:41:55
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 17:59:29
User entered 'Adverse Event (AE)'	Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:05:06

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:03:13

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:16
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	25 Mar 2021 20:05:06
	(b) (4)	

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:03:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:16
User entered '23 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:05:41

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:03:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:16
User entered 'BONE MARROW BIOPSY'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Mar 2021 20:05:41

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:03:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:16
	(b) (4)	
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	25 Mar 2021 20:06:32
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	25 Mar 2021 20:05:41
User entered 'Adverse Event (AE)'	Karol Moore (b) (4)	25 Mar 2021 20:05:41
	(b) (4)	

US3312224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:03:13

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:50:06
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:46:16
User entered empty; reason for change Data Entry Error	(b) (4)	25 Mar 2021 20:06:32
User entered 'thrombocytopenia'	Karol Moore (b) (4)	25 Mar 2021 20:05:41
	(b) (4)	

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'USA-US300-2021-MRNA-1273-P301000018'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
Un-reviewed for Safety.	System	09 Apr 2021 17:53:12
DataPoint Un-verified.	System	09 Apr 2021 17:53:12
Signature has been broken.	System	09 Apr 2021 17:53:12
User entered 'Yes (Y)'	System	09 Apr 2021 17:53:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Carlos'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Fierro'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '16300 College Blvd'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Shawnee'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'KS'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '66219'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered 'US'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 16:12:48
User entered '7'	System	12 Apr 2021 12:57:44
User entered '6'	System	09 Apr 2021 13:47:42
User entered '5'	System	08 Apr 2021 13:32:54
User entered '4'	System	05 Apr 2021 16:24:44
User entered '3'	System	26 Mar 2021 18:10:49
User entered '2'	System	25 Mar 2021 18:15:07
User entered '1'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'USA-US300-2021-MRNA-1273-P301000018'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
Un-reviewed for Safety.	System	09 Apr 2021 17:53:12
DataPoint Un-verified.	System	09 Apr 2021 17:53:12
Signature has been broken.	System	09 Apr 2021 17:53:12
User entered 'Yes (Y)'	System	09 Apr 2021 17:53:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Carlos'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Fierro'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '16300 College Blvd'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Shawnee'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'KS'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '66219'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered 'US'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 16:12:48
User entered '7'	System	12 Apr 2021 12:57:44
User entered '6'	System	09 Apr 2021 13:47:42
User entered '5'	System	08 Apr 2021 13:32:54
User entered '4'	System	05 Apr 2021 16:24:44
User entered '3'	System	26 Mar 2021 18:10:49
User entered '2'	System	25 Mar 2021 18:15:07
User entered '1'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:03:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered '23/Feb/2021 09:18'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:03:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered 'I'	(b) (4), (b) (6)	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'USA-US300-2021-MRNA-1273-P301000018'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
Un-reviewed for Safety.	System	09 Apr 2021 17:53:12
DataPoint Un-verified.	System	09 Apr 2021 17:53:12
Signature has been broken.	System	09 Apr 2021 17:53:12
User entered 'Yes (Y)'	System	09 Apr 2021 17:53:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Carlos'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Fierro'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '16300 College Blvd'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Shawnee'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'KS'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '66219'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered 'US'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 16:12:48
User entered '7'	System	12 Apr 2021 12:57:44
User entered '6'	System	09 Apr 2021 13:47:42
User entered '5'	System	08 Apr 2021 13:32:54
User entered '4'	System	05 Apr 2021 16:24:44
User entered '3'	System	26 Mar 2021 18:10:49
User entered '2'	System	25 Mar 2021 18:15:07
User entered '1'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:03:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '25/Mar/2021 18:15'	(b) (4) System	25 Mar 2021 18:15:07

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:03:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:10:32
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 18:15:07

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'USA-US300-2021-MRNA-1273-P301000018'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
Un-reviewed for Safety.	System	09 Apr 2021 17:53:12
DataPoint Un-verified.	System	09 Apr 2021 17:53:12
Signature has been broken.	System	09 Apr 2021 17:53:12
User entered 'Yes (Y)'	System	09 Apr 2021 17:53:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Carlos'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Fierro'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '16300 College Blvd'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Shawnee'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'KS'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '66219'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered 'US'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 16:12:48
User entered '7'	System	12 Apr 2021 12:57:44
User entered '6'	System	09 Apr 2021 13:47:42
User entered '5'	System	08 Apr 2021 13:32:54
User entered '4'	System	05 Apr 2021 16:24:44
User entered '3'	System	26 Mar 2021 18:10:49
User entered '2'	System	25 Mar 2021 18:15:07
User entered '1'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:03:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '26/Mar/2021 13:10'	(b) (4) System	26 Mar 2021 18:10:49

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:03:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:24:25
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 18:10:49

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'USA-US300-2021-MRNA-1273-P301000018'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
Un-reviewed for Safety.	System	09 Apr 2021 17:53:12
DataPoint Un-verified.	System	09 Apr 2021 17:53:12
Signature has been broken.	System	09 Apr 2021 17:53:12
User entered 'Yes (Y)'	System	09 Apr 2021 17:53:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Carlos'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Fierro'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '16300 College Blvd'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Shawnee'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'KS'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '66219'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered 'US'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 16:12:48
User entered '7'	System	12 Apr 2021 12:57:44
User entered '6'	System	09 Apr 2021 13:47:42
User entered '5'	System	08 Apr 2021 13:32:54
User entered '4'	System	05 Apr 2021 16:24:44
User entered '3'	System	26 Mar 2021 18:10:49
User entered '2'	System	25 Mar 2021 18:15:07
User entered '1'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:03:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered '05/Apr/2021 12:24'	(b) (4) System	05 Apr 2021 16:24:44

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:03:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:24:44

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'USA-US300-2021-MRNA-1273-P301000018'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
Un-reviewed for Safety.	System	09 Apr 2021 17:53:12
DataPoint Un-verified.	System	09 Apr 2021 17:53:12
Signature has been broken.	System	09 Apr 2021 17:53:12
User entered 'Yes (Y)'	System	09 Apr 2021 17:53:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Carlos'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Fierro'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '16300 College Blvd'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Shawnee'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'KS'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '66219'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered 'US'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 16:12:48
User entered '7'	System	12 Apr 2021 12:57:44
User entered '6'	System	09 Apr 2021 13:47:42
User entered '5'	System	08 Apr 2021 13:32:54
User entered '4'	System	05 Apr 2021 16:24:44
User entered '3'	System	26 Mar 2021 18:10:49
User entered '2'	System	25 Mar 2021 18:15:07
User entered '1'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:03:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:51
User entered '08/Apr/2021 06:32'	(b) (4) System	08 Apr 2021 13:32:54

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:03:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:32:54

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'USA-US300-2021-MRNA-1273-P301000018'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
Un-reviewed for Safety.	System	09 Apr 2021 17:53:12
DataPoint Un-verified.	System	09 Apr 2021 17:53:12
Signature has been broken.	System	09 Apr 2021 17:53:12
User entered 'Yes (Y)'	System	09 Apr 2021 17:53:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Carlos'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Fierro'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '16300 College Blvd'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Shawnee'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'KS'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '66219'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered 'US'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 16:12:48
User entered '7'	System	12 Apr 2021 12:57:44
User entered '6'	System	09 Apr 2021 13:47:42
User entered '5'	System	08 Apr 2021 13:32:54
User entered '4'	System	05 Apr 2021 16:24:44
User entered '3'	System	26 Mar 2021 18:10:49
User entered '2'	System	25 Mar 2021 18:15:07
User entered '1'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:03:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:21
User entered '09/Apr/2021 09:47'	(b) (4) System	09 Apr 2021 13:47:42

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:03:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:47:42

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'USA-US300-2021-MRNA-1273-P301000018'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
Un-reviewed for Safety.	System	09 Apr 2021 17:53:12
DataPoint Un-verified.	System	09 Apr 2021 17:53:12
Signature has been broken.	System	09 Apr 2021 17:53:12
User entered 'Yes (Y)'	System	09 Apr 2021 17:53:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Carlos'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Fierro'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '16300 College Blvd'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Shawnee'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'KS'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '66219'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered 'US'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 16:12:48
User entered '7'	System	12 Apr 2021 12:57:44
User entered '6'	System	09 Apr 2021 13:47:42
User entered '5'	System	08 Apr 2021 13:32:54
User entered '4'	System	05 Apr 2021 16:24:44
User entered '3'	System	26 Mar 2021 18:10:49
User entered '2'	System	25 Mar 2021 18:15:07
User entered '1'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:03:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
User entered '12/Apr/2021 05:57'	(b) (4) System	12 Apr 2021 12:57:44

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:03:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 12:57:44
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 12:57:44
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:58:21
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:47:42

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'USA-US300-2021-MRNA-1273-P301000018'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Yes (Y)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
	(b) (4)	
Un-reviewed for Safety.	System	09 Apr 2021 17:53:12
DataPoint Un-verified.	System	09 Apr 2021 17:53:12
Signature has been broken.	System	09 Apr 2021 17:53:12
User entered 'Yes (Y)'	System	09 Apr 2021 17:53:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'No (N)'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Carlos'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Fierro'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '16300 College Blvd'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'Shawnee'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered 'KS'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:10:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 14:18:09
User entered '66219'	System	23 Feb 2021 14:16:53

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:10:56
User entered 'US'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 16:12:48
User entered '7'	System	12 Apr 2021 12:57:44
User entered '6'	System	09 Apr 2021 13:47:42
User entered '5'	System	08 Apr 2021 13:32:54
User entered '4'	System	05 Apr 2021 16:24:44
User entered '3'	System	26 Mar 2021 18:10:49
User entered '2'	System	25 Mar 2021 18:15:07
User entered '1'	System	23 Feb 2021 14:18:18

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:03:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	28 Apr 2021 21:58:42
User entered '27/Apr/2021 09:12'	(b) (4) System	27 Apr 2021 16:12:48

US3312224

Folder: SAE USA-US300-2021-MRNA-1273-P301000018

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:03:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	28 Apr 2021 21:58:42
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 16:12:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 16:12:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:21
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 12:57:30