

US3312325 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:59:14

All time stamps listed in this document are displayed in GMT

US3312325

Form: Participant Creation

Data signed: (b) (4) 06 Apr 2021 01:22:18

Generated On: 09 Jun 2021 16:59:14

Participant ID

US3312325

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

US3312325

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3312325

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3312325

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Date of Informed Consent (<i>dd MMM yyyy</i>)	27 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 type="radio"/>
	Amendment 3 <input checked="" 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

US3312325

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3312325

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Were any significant conditions reported?

Yes ☒

No ☐

US3312325

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312325

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	UTERINE FIBROID TUMORS
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

US3312325

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

US3312325

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	BILATERAL SALPINGO-OOPHORECTOMY
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

US3312325

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	RIGHT FOOT NEUROMA
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3312325

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	RIGHT FOOT NEUROMA REMOVAL
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3312325

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

US3312325

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	ALLERGY TO CODEINE
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

US3312325

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	ALLERGY TO TETRACYCLINE
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

US3312325

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	OSTEOARTHRITIS
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)	_____

US3312325

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	RECTOCELE
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)	

US3312325

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Condition	CYSTOCELE
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)	_____

US3312325

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 10:37
Height (xxx.x)	64 in
Weight (xxx.x)	161.4 lb
BMI (xxx.x)	27.76217 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312325

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3312325

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Date of assessment (dd MMM yyyy) 27 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1996

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

US3312325

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3312325

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 188553

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 ☒

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Height	ND - Not Done
Weight	ND - Not Done

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

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)	27 AUG 2020
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 10:37
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

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)	27 AUG 2020
Time of assessment (00:00-23:59)	12:24 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 12:24
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3312325

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

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.

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 11:53 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 11:53

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

US3312325

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 AUG 2020
Collection time (00:00-23:59)	11:15 (24 HR)
Collection date and time (derived)	27 AUG 2020 11:15

US3312325

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:11	27 AUG 2020 11:11
Nasopharyngeal Swab 2	No		

US3312325

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:24

PC Open Date & Time

27 AUG 2020 12:13

PC Close Date & Time

27 AUG 2020 14:43

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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	27 AUG 2020 18:39
PC Open Date & Time	27 AUG 2020 15:38
PC Close Date & Time	28 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

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

98.1 °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 18:05

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

29 AUG 2020 19:54

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

30 AUG 2020 22:47

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 19:10

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

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

97.6 °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

01 SEP 2020 18:44

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 03:57

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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

27 AUG 2020 12:25

PC Open Date & Time

27 AUG 2020 12:13

PC Close Date & Time

27 AUG 2020 14:43

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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

28 AUG 2020 10:37

PC Open Date & Time

27 AUG 2020 15:38

PC Close Date & Time

28 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

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

28 AUG 2020 18:06

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

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

29 AUG 2020 19:55

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

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

30 AUG 2020 22:48

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

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

31 AUG 2020 19:11

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

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

01 SEP 2020 18:44

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

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

03 SEP 2020 03:58

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 12:26
PC Open Date & Time	27 AUG 2020 12:13
PC Close Date & Time	27 AUG 2020 14:43

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 18:43
PC Open Date & Time	27 AUG 2020 15:38
PC Close Date & Time	28 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

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 ☒

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 18:06
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

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

57 of 2254

EAB) (1725)

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:55
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

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

59 of 2254

EAB) (1725)

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 22:48
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

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

61 of 2254

EAB) (1725)

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 19:11
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

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 ☒

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 18:45
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

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 ☒

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 03:58
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3312325

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:37:59

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:37:59

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:37:59

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:37:59

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

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 SEP 2020
Time of assessment (00:00-23:59)	10:08 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:08
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 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)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

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 SEP 2020
Time of assessment (00:00-23:59)	11:41 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 11:41
Temperature (xxx.x)	97.9 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)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3312325

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

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 SEP 2020

What was the treatment time? (00:00-23:59) 11:10 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 11:10

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

US3312325

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

24 SEP 2020 10:30

US3312325

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:26	24 SEP 2020 10:26
Nasopharyngeal Swab 2	No		

US3312325

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 11:44

PC Open Date & Time

24 SEP 2020 11:30

PC Close Date & Time

24 SEP 2020 14:00

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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 19:16

PC Open Date & Time

24 SEP 2020 14:55

PC Close Date & Time

25 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

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

25 SEP 2020 19:46

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

27 SEP 2020 00:11

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

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

97.5 °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

28 SEP 2020 12:25

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 19:12

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

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

98.2 °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 SEP 2020 22:53

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 11:45

PC Open Date & Time

24 SEP 2020 11:30

PC Close Date & Time

24 SEP 2020 14:00

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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 SEP 2020 19:17

PC Open Date & Time

24 SEP 2020 14:55

PC Close Date & Time

25 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

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 SEP 2020 19:47

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

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

27 SEP 2020 00:12

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

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 SEP 2020 12:35

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

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 SEP 2020 19:13

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

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 SEP 2020 22:53

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 11:45
PC Open Date & Time	24 SEP 2020 11:30
PC Close Date & Time	24 SEP 2020 14:00

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 19:17
PC Open Date & Time	24 SEP 2020 14:55
PC Close Date & Time	25 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

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 ☒

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 19:47
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

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

103 of 2254

EAB) (1725)

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

105 of 2254

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

Yes ☐

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

107 of 2254

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 12:35
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

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 ☒

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 19:13
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

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

111 of 2254

EAB) (1725)

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 22:54
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3312325

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:38:00

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 10:15
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312325

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

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.

US3312325

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

10:20 (24 HR)

Collection date and time (derived)

22 OCT 2020 10:20

US3312325

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:38:01

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 15:45:41

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 <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	05 NOV 2020 12:38:12
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 23:37:45

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 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	25 NOV 2020 17:20:34
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 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	30 NOV 2020 19:29:32
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 18:00:01

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 DEC 2020 19:50:53
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 15:56:00

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 14:32:09

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 12:01:20

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 22:00:55

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 09:56:08

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

25 JAN 2021 12:30:21

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

02 FEB 2021 07:54:39

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 13:11:58
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

15 FEB 2021 20:25:44

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 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	22 FEB 2021 12:16:48
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 18:12:09

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 20:02:07
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 22:07:04

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 20:24:07

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

29 MAR 2021 16:20:06

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

04 APR 2021 09:37:49

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

12 APR 2021 13:29:15

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 21:58:25

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

26 APR 2021 09:29:27

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

03 MAY 2021 12:05:21

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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°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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 264

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

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

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

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

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

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

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	02 OCT 2021 00:01
Patient Cloud Close Date & Time	06 OCT 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 NOV 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	17 NOV 2021 23:59
---	-------------------

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 <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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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="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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	27 NOV 2021 00:01
Patient Cloud Close Date & Time	01 DEC 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐
Yes ☐

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 <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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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°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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	17 AUG 2022 23:59
---	-------------------

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 726

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

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

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

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

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

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

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3312325

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:59:14

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
Yes	No	01 MAR 2021 18:13:16

US3312325

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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

Visit date (dd MMM yyyy)	15 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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) _____

US3312325

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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.

US3312325

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	10:13 (24 HR)
Collection date and time (derived)	15 MAR 2021 10:13

US3312325

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312325

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:59:14

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"/>

US3312325

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:59:14

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3312325

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

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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

Visit date (dd MMM yyyy)	11 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
------------	---------------

US3312325

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

Form: Unblinding

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 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>)	11 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

US3312325

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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

US3312325

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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)	11 JAN 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 10:20
Temperature (xxx.x)	98.4 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)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3312325

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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)	11 JAN 2021
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 12:06
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3312325

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

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3312325

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

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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) 11 JAN 2021

What was the treatment time? (00:00-23:59) 11:35 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 11:35

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

US3312325

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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

Collection date (dd MMM yyyy)	11 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	09:49 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	11 JAN 2021 09:49
------------------------------------	-------------------

US3312325

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	09:48
Collection Date and Time (derived)	11 JAN 2021 09:48

US3312325

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

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312325

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:23:13

Generated On: 09 Jun 2021 16:59:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Apr 2021 01:23:13

Generated On: 09 Jun 2021 16:59:14

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)	08 FEB 2021
Time of assessment (00:00-23:59)	09:26 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 09:26
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Apr 2021 01:23:13

Generated On: 09 Jun 2021 16:59:14

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)	08 FEB 2021
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 10:45
Temperature (xxx.x)	98.6 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)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3312325

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:23:13

Generated On: 09 Jun 2021 16:59:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 FEB 2021

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

US3312325

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 06 Apr 2021 01:23:13

Generated On: 09 Jun 2021 16:59:14

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) 08 FEB 2021

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 10:15

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

US3312325

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:23:13

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312325

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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) _____

US3312325

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

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.

US3312325

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 01:23:13

Generated On: 09 Jun 2021 16:59:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	15 MAR 2021
Collection time (<i>00:00-23:59</i>)	10:13 (24 HR)
Collection date and time (derived)	15 MAR 2021 10:13

US3312325

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:56:09

Generated On: 09 Jun 2021 16:59:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:56:09

Generated On: 09 Jun 2021 16:59:14

AEID

Adverse event

URINARY TRACT INFECTION

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)

31 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 NOV 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

350 of 2254

EAB) (1725)

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:56:09

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 15:56:09

Generated On: 09 Jun 2021 16:59:14

AEID	USA-US300-2020-MRNA-1273-P30 1000020
Adverse event	WORSENING OF PELVIC ORGAN PROLAPSE
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)	11 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	12 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	352 of 2254

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 15:56:09

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 15:56:09

Generated On: 09 Jun 2021 16:59:14

71 YEAR OLD FEMALE WITH
DISTANT HISTORY OF
HYSTEROSALPINGECTOMY
AND A 5 YEAR HISTORY OF
SLOWLY PROGRESSIVE
RECTOCELE WAS ADVISED BY
PCP AT RECENT ANNUAL
PHYSICAL TO REPAIR
SURGICALLY. SUBJECT DID
NOT PERCEIVE SIGNIFICANT
WORSENING AND CONSIDERED
THE OPTION FOR MONTHS
PRIOR TO RECENTLY
UNDERGOING THE
PROCEDURE. SHE WAS
HOSPITALIZED FOR MORE
THAN 24 HOURS AS PART OF
THE SURGERY, WHICH WENT
WITHOUT COMPLICATIONS.
SHE WAS ADMITTED 11DEC2020
THROUGH 12DEC2020 AND WAS
DISCHARGED ON PAIN
MEDICATIONS. HER COVID
TEST WAS NEGATIVE. SHE
SOUNDS WELL ON THE PHONE
CALL TODAY. POST OP
FOLLOW-UP WITH HER
GYNECOLOGIST IS 23DEC2020.
WILL OBTAIN MED RECORDS.
UPDATE:MEDICAL RECORDS
RECEIVED, CONFIRMING THAT
SUBJECT UNDERWENT
ELECTIVE SURGICAL
PROCEDURE TO REPAIR
RECTOCELE BUT ALSO

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 15:56:09

Generated On: 09 Jun 2021 16:59:14

CYSTOCELE. PROCEDURE WAS
ANTERIOR AND POSTERIOR
REPAIR, SACROSPINOUS
FIXATION, PERINORRHAPHY,
AND CYSTOSCOPY. PATIENT
TOLERATED IT WELL AND HAD
NO COMPLICATIONS. WILL
CLOSE SAE, NOT RELATED TO
IP, OF MODERATE SEVERITY.

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

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 15:18:56

Generated On: 09 Jun 2021 16:59:14

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

Yes ☒

No ☐

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

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication SYMBICORT
(BUDESONIDE/FORMOTEROL)

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 80/4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication ALBUTEROL (90MCG)

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

359 of 2254

EAB) (1725)

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1970	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH
MAINTENANCE

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication COLLAGEN (POWDER)

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH
MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify TEASPOON

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

363 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

365 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication CETRIZINE

Prophylaxis Yes ☐
No ☒

Indication ALLERGY TO RHINITIS

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)

367 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication DOXYLAMINE SUCCINATE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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

NIGHTLY

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication FLUZONE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL INFLUENZA
PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

371 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication TRIMETHOPRIM/SULFAMETHO
XAZOLE

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 800/160

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

	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)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication TRIMETHOPRIM/SULFAMETHO
XAZOLE

Prophylaxis Yes ☒
No ☐

Indication POST SURGERY INFECTION
PROPHYLAXIS

Dose per administration 800/160

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

375 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

	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)	17 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF PELVIC ORGAN
PROLAPSA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

377 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

	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)		11 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication ESTRADIOL CREAM

Prophylaxis Yes ☐
No ☒

Indication RECTOCELE REPAIR

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input checked="" 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)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 29 JAN 2021		
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/>	
	No <input 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"/>	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication DYSPORE

Prophylaxis Yes ☒
No ☐

Indication COSMETIC PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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)

381 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

Name of Medication ESTRADIOL CREAM

Prophylaxis Yes ☐
No ☒

Indication RECTOCELE REPAIR

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONCE EVERY 3 DAYS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2254

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 18:09:51

Generated On: 09 Jun 2021 16:59:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input checked="" 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)	30 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 06 Apr 2021 01:23:13

Generated On: 09 Jun 2021 16:59:14

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Apr 2021 01:22:18

Generated On: 09 Jun 2021 16:59:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 DEC 2020	RECTOCELE/CYSTOCELE REPAIR	Adverse Event	
11 DEC 2020	SACROSPINOUS FIXATION	Adverse Event	
11 DEC 2020	PERINEORRHAPHY	Adverse Event	
11 DEC 2020	CYSTOSCOPY	Adverse Event	

US3312325

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:59:14

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

US3312325

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:59:14

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 ☐

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

SAEID	USA-US300-2020-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

SAEID	USA-US300-2020-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2
Date of submission (Pre-filled from custom function)	17/DEC/2020 15:22
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

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 06 Apr 2021 01:23:14

Generated On: 09 Jun 2021 16:59:14

SAEID	USA-US300-2020-MRNA-1273-P301000020
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	2
Date of submission (Pre-filled from custom function)	08/JAN/2021 08:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3312325 (Prod: Johnson County Clin-Trials)

US3312325

Form: Participant Creation

Generated On: 09 Jun 2021 16:59:14

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:20:45
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered 'US3312325'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 15:09:55

US3312325

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:21
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:26

US3312325

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:21
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 15:09:56

US3312325

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[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 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:21
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:26

US3312325

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'SCRN'	System	27 Aug 2020 16:57:26

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 15:09:57

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered '71'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'YEARS'	System	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '71'	System	27 Aug 2020 16:57:38

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered 'Female (F)'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered 'l'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered '0'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered '0'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered '0'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered '0'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered '0'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered empty.	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered '0'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:33
User entered '0'	Monica Atwood (b) (4) (b) (4)	02 Sep 2020 15:57:17

US3312325

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:14

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:38
User entered '27 Aug 2020'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:38

US3312325

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Aug 2020'	System	27 Aug 2020 16:57:38

US3312325

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '2020'	System	27 Aug 2020 16:57:38

US3312325

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:38
User entered 'Amendment 3 (3)' reason for change:	Karol Moore (b) (4)	27 Aug 2020 19:32:14
Data Entry Error	(b) (4)	
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:38

US3312325

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:38
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:38

US3312325

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:14

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:38
User entered empty.	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:38

US3312325

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:38
User entered empty.	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:38

US3312325

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:38
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:38

US3312325

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:27:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 15:09:56

US3312325

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'I'	System	27 Aug 2020 16:57:44

US3312325

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:28:50
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:44

US3312325

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:59:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:50
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:09

US3312325

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:19:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:19:43
Data point term sent to Coder	System	04 Sep 2020 18:19:08
User entered 'ASTHMA'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:30

US3312325

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 1970'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:30

US3312325

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:30

US3312325

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:30

US3312325

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:30

US3312325

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:30

US3312325

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 1970'	System	04 Sep 2020 18:18:30

US3312325

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1970'	System	04 Sep 2020 18:18:30

US3312325

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:18:30

US3312325

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:18:30

US3312325

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroid - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:19:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:19:43
Data point term sent to Coder	System	04 Sep 2020 18:19:08
User entered 'UTERINE FIBROID TUMORS'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:54

US3312325

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 1996'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:54

US3312325

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:54

US3312325

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:54

US3312325

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 1996'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:54

US3312325

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:18:54

US3312325

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 1996'	System	04 Sep 2020 18:18:54

US3312325

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1996'	System	04 Sep 2020 18:18:54

US3312325

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 1996'	System	04 Sep 2020 18:18:54

US3312325

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1996'	System	04 Sep 2020 18:18:54

US3312325

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:20:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:20:45
Data point term sent to Coder	System	04 Sep 2020 18:20:12
User entered 'HYSTERECTOMY'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:19:16

US3312325

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 1996'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:19:16

US3312325

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:19:16

US3312325

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:19:16

US3312325

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 1996'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:19:16

US3312325

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:19:16

US3312325

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 1996'	System	04 Sep 2020 18:19:16

US3312325

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1996'	System	04 Sep 2020 18:19:16

US3312325

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 1996'	System	04 Sep 2020 18:19:16

US3312325

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1996'	System	04 Sep 2020 18:19:16

US3312325

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Fallopian tube therapeutic procedures, PT: Salpingo-oophorectomy bilateral, LLT: Bilateral salpingo-oophorectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:21:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:21:46
Data point term sent to Coder	System	04 Sep 2020 18:21:15
User entered 'Bilateral salpingo-oophorectomy'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:32

US3312325

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 1996'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:32

US3312325

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:32

US3312325

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:32

US3312325

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 1996'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:32

US3312325

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:32

US3312325

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 1996'	System	04 Sep 2020 18:20:32

US3312325

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1996'	System	04 Sep 2020 18:20:32

US3312325

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 1996'	System	04 Sep 2020 18:20:32

US3312325

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1996'	System	04 Sep 2020 18:20:32

US3312325

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Nervous system neoplasms benign, HLT: Neuromas, PT: Neuroma, LLT: Neuroma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:17:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:17:50
Data point term sent to Coder	System	04 Sep 2020 18:21:15
User entered 'RIGHT FOOT NEUROMA'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:49

US3312325

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 2008'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:49

US3312325

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:49

US3312325

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:49

US3312325

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 2008'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:49

US3312325

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:20:49

US3312325

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 2008'	System	04 Sep 2020 18:20:49

US3312325

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '2008'	System	04 Sep 2020 18:20:49

US3312325

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 2008'	System	04 Sep 2020 18:20:49

US3312325

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '2008'	System	04 Sep 2020 18:20:49

US3312325

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Nervous system therapeutic procedures NEC, PT: Neurectomy, LLT: Neuroma removal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:17:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:17:50
Data point term sent to Coder	System	04 Sep 2020 18:21:18
User entered 'RIGHT FOOT NEUROMA REMOVAL'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:07

US3312325

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 2008'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:07

US3312325

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:07

US3312325

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:07

US3312325

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 2008'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:07

US3312325

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:07

US3312325

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 2008'	System	04 Sep 2020 18:21:07

US3312325

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '2008'	System	04 Sep 2020 18:21:07

US3312325

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 2008'	System	04 Sep 2020 18:21:07

US3312325

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '2008'	System	04 Sep 2020 18:21:07

US3312325

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:21:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:21:45
Data point term sent to Coder	System	04 Sep 2020 18:21:19
User entered 'INSOMNIA'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:17

US3312325

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 2010'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:17

US3312325

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:17

US3312325

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:17

US3312325

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:17

US3312325

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:17

US3312325

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 2010'	System	04 Sep 2020 18:21:17

US3312325

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '2010'	System	04 Sep 2020 18:21:17

US3312325

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:21:17

US3312325

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:21:17

US3312325

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:23:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:23:39
Data point term sent to Coder	System	04 Sep 2020 18:22:20
User entered 'ALLERGIC RHINITIS'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:29

US3312325

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 1970'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:29

US3312325

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:29

US3312325

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:29

US3312325

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:29

US3312325

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:29

US3312325

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 1970'	System	04 Sep 2020 18:21:29

US3312325

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1970'	System	04 Sep 2020 18:21:29

US3312325

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:21:29

US3312325

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:21:29

US3312325

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:59:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:23:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:23:40
Data point term sent to Coder	System	04 Sep 2020 18:22:22
User entered 'ALLERGY TO CODEINE'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:51

US3312325

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 1980'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:51

US3312325

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:51

US3312325

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:51

US3312325

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:51

US3312325

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:21:51

US3312325

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 1980'	System	04 Sep 2020 18:21:51

US3312325

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1980'	System	04 Sep 2020 18:21:51

US3312325

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:21:51

US3312325

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:21:51

US3312325

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
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: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 15:38:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 15:38:49
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 18:23:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 18:23:40
Data point term sent to Coder	System	04 Sep 2020 18:22:22
User entered 'ALLERGY TO TETRACYCLINE'	Karol Moore (b) (4)	04 Sep 2020 18:22:08

US3312325

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 1975'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:08

US3312325

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:08

US3312325

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:08

US3312325

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:08

US3312325

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:08

US3312325

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 1975'	System	04 Sep 2020 18:22:08

US3312325

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1975'	System	04 Sep 2020 18:22:08

US3312325

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:22:08

US3312325

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:22:08

US3312325

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:23:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:23:40
Data point term sent to Coder	System	04 Sep 2020 18:22:22
User entered 'OSTEOARTHRITIS'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:21

US3312325

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'UN UNK 2015'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:21

US3312325

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:21

US3312325

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:21

US3312325

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:21

US3312325

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:31:07
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:21

US3312325

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 2015'	System	04 Sep 2020 18:22:21

US3312325

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '2015'	System	04 Sep 2020 18:22:21

US3312325

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:22:21

US3312325

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:22:21

US3312325

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Pelvic prolapse conditions, PT: Rectocele, LLT: Rectocele - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 20:01:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 20:01:57
Data point term sent to Coder	System	16 Dec 2020 20:00:22
User entered 'rectocele'	(b) (4), (b) (6)	16 Dec 2020 20:00:17

US3312325

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:00:17

US3312325

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:00:17

US3312325

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:00:17

US3312325

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:00:17

US3312325

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:00:17

US3312325

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 2015'	System	16 Dec 2020 20:00:17

US3312325

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '2015'	System	16 Dec 2020 20:00:17

US3312325

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	16 Dec 2020 20:00:17

US3312325

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	16 Dec 2020 20:00:17

US3312325

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:59:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Pelvic prolapse conditions, PT: Cystocele, LLT: Cystocele - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 19:14:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 19:14:51
Data point term sent to Coder	System	10 Feb 2021 19:14:26
User entered 'cYSTOCELE' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 19:14:05
User entered 'systocele'	(b) (4), (b) (6)	10 Feb 2021 19:13:55

US3312325

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:13:55

US3312325

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:13:55

US3312325

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:59:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:13:55

US3312325

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:13:55

US3312325

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:59:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:13:55

US3312325

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:59:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'Jan 2015'	System	10 Feb 2021 19:13:55

US3312325

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '2015'	System	10 Feb 2021 19:13:55

US3312325

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	10 Feb 2021 19:13:55

US3312325

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	10 Feb 2021 19:13:55

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered '27 Aug 2020'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered '10:37'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '27 Aug 2020 10:37'	System	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered '64' in	Karol Moore (b) (4)	04 Sep 2020 18:22:45
DataPoint set to visible.	(b) (4) System	27 Aug 2020 16:57:44

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered '161.4' lb	Karol Moore (b) (4)	04 Sep 2020 18:22:45
DataPoint set to visible.	(b) (4) System	27 Aug 2020 16:57:44

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '27.76217'	System	04 Sep 2020 18:22:45
DataPoint set to visible.	System	27 Aug 2020 16:57:44

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'kg/m2'	System	04 Sep 2020 18:22:45
DataPoint set to visible.	System	27 Aug 2020 16:57:44

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'bpm'	System	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'breaths/min'	System	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'mmHg'	System	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:32:23
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'mmHg'	System	04 Sep 2020 18:22:45

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22

US3312325

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22

US3312325

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:33:41
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:53

US3312325

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:33:41
User entered '27 Aug 2020'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:22:53

US3312325

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:42
User entered '27 Aug 2020'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:12

US3312325

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:14

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:42
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:12

US3312325

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:14

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:42
User entered 'Surgically sterile (SURGICALLY STERILE)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:12

US3312325

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:14

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:42
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:12

US3312325

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:42
User entered 'UN UNK 1996'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:12

US3312325

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:14

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:42
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:12

US3312325

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:42
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:12

US3312325

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:14

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:42
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:12

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:29:09
User entered 'RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:23:52

US3312325

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:38
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:54

US3312325

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:38
User entered '27 Aug 2020'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:54

US3312325

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[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 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:38
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:57:54

US3312325

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'VISIT1'	System	27 Aug 2020 16:57:54

US3312325

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:09
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 16:25:27

US3312325

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:14

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:09
User entered '188553'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 16:25:27

US3312325

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:14

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:09
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 16:25:27

US3312325

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:14

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)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:09
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:05

US3312325

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:14

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)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:09
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:05

US3312325

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:14

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:09
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:05

US3312325

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:14

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:09
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:05

US3312325

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:09
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:05

US3312325

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:14

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:27:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'No (N)'	(b) (4) Heather Barker (b) (4)	30 Oct 2020 18:22:36
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:13:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:13:46

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '27 Aug 2020'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '10:37'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '27 Aug 2020 10:37'	System	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '98.3' F	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '76'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'bpm'	System	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '14'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'breaths/min'	System	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '108'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'mmHg'	System	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '65'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'mmHg'	System	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '27 Aug 2020'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '12:24'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '27 Aug 2020 12:24'	System	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '97.9' F	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '65'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'bpm'	System	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '16'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'breaths/min'	System	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '110'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'mmHg'	System	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 07:15:46
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Correct as entered NCS. Not an AE. Per protocol toxicity table, diastolic blood pressure not defined.' (Site from System).	Heather Barker (b) (4) (b) (4)	21 Oct 2020 20:04:08
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:05:11
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:36:04
User entered '59'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'mmHg'	System	04 Sep 2020 18:24:53

US3312325

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:33:34
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:00

US3312325

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:33:34
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:00

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:50
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:30

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:50
User entered empty.	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:30

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

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 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:50
User entered empty.	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:30

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 16:58:30

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:50
User entered '27 Aug 2020'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:30

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:50
User entered '11:53'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:30

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '27 Aug 2020 11:53'	System	27 Aug 2020 16:58:30

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:50
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4) (b) (4)	27 Aug 2020 16:58:30

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:34:50
User entered 'ONCE'	System	27 Aug 2020 16:58:30

US3312325

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 16:58:30

US3312325

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:56
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:18

US3312325

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:56
User entered '27 Aug 2020'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:18

US3312325

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:34:56
User entered '11:15' reason for change: Data Entry Error	Karol Moore (b) (4)	04 Sep 2020 18:25:49
User entered '11:11'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:18

US3312325

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '27 Aug 2020 11:15'	System	04 Sep 2020 18:25:49
User entered '27 Aug 2020 11:11'	System	04 Sep 2020 18:25:18

US3312325

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:59:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:00
User entered '27 Aug 2020'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:33

US3312325

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:33

US3312325

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:00
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:33

US3312325

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:00
User entered '11:11'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:33

US3312325

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '27 Aug 2020 11:11'	System	04 Sep 2020 18:25:33

US3312325

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:33

US3312325

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:00
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:33

US3312325

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:35:00
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:33

US3312325

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered empty.	System	04 Sep 2020 18:25:33

US3312325

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:36:17
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:25:39

US3312325

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered '1'	System	04 Sep 2020 18:25:39

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:23:56', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b6e813ea-828e-414d-a178-bcca85b4de1a' User entered 'Yes (Y)'	System	27 Aug 2020 17:24:20
	System	27 Aug 2020 17:24:20

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:24:03', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b6e813ea-828e-414d-a178-bcca85b4de1a' User entered '97.9'	System	27 Aug 2020 17:24:20
	System	27 Aug 2020 17:24:20

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:24:12', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b6e813ea-828e-414d-a178-bcca85b4de1a' User entered 'No (N)'	System	27 Aug 2020 17:24:20
	System	27 Aug 2020 17:24:20

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:24:18', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b6e813ea-828e-414d-a178-bcca85b4de1a' User entered '27 Aug 2020 12:24'	System	27 Aug 2020 17:24:20
	System	27 Aug 2020 17:24:20

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Aug 2020 12:13'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Aug 2020 14:43'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:39:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'a315f4e0-46b9-4f53-ab42-12178fa3f3f1' User entered 'Yes (Y)'	System	27 Aug 2020 23:39:34
	System	27 Aug 2020 23:39:34

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:39:10', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'a315f4e0-46b9-4f53-ab42-12178fa3f3f1' User entered '98.5'	System	27 Aug 2020 23:39:34
	System	27 Aug 2020 23:39:34

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:39:16', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'a315f4e0-46b9-4f53-ab42-12178fa3f3f1'	System	27 Aug 2020 23:39:34
User entered 'No (N)'	System	27 Aug 2020 23:39:34

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:39:30', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'a315f4e0-46b9-4f53-ab42-12178fa3f3f1' User entered '27 Aug 2020 18:39'	System	27 Aug 2020 23:39:34
	System	27 Aug 2020 23:39:34

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Aug 2020 15:38'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 2'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:02:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2d3742c2-9fc5-4d07-9e97-03acc0601293'	System	28 Aug 2020 23:05:14
User entered 'Yes (Y)'	System	28 Aug 2020 23:05:14

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:04:51', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2d3742c2-9fc5-4d07-9e97-03acc0601293' User entered '98.1'	System	28 Aug 2020 23:05:14
	System	28 Aug 2020 23:05:14

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:04:56', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2d3742c2-9fc5-4d07-9e97-03acc0601293'	System	28 Aug 2020 23:05:14
User entered 'No (N)'	System	28 Aug 2020 23:05:14

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:05:08', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2d3742c2-9fc5-4d07-9e97-03acc0601293'	System	28 Aug 2020 23:05:14
User entered '28 Aug 2020 18:05'	System	28 Aug 2020 23:05:14

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 3'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:54:05', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '44f43892-6d3b-4cc4-89c6-06f7799ec82a' User entered 'Yes (Y)'	System	30 Aug 2020 00:54:39
	System	30 Aug 2020 00:54:39

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:54:24', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '44f43892-6d3b-4cc4-89c6-06f7799ec82a' User entered '97.7'	System	30 Aug 2020 00:54:39
	System	30 Aug 2020 00:54:39

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:54:29', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '44f43892-6d3b-4cc4-89c6-06f7799ec82a' User entered 'No (N)'	System	30 Aug 2020 00:54:39
	System	30 Aug 2020 00:54:39

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:54:36', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '44f43892-6d3b-4cc4-89c6-06f7799ec82a' User entered '29 Aug 2020 19:54'	System	30 Aug 2020 00:54:39
	System	30 Aug 2020 00:54:39

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 4'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:45:14', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2cf0327a-83ec-4e60-ae41-951ed956532c' User entered 'Yes (Y)'	System	31 Aug 2020 03:47:38
	System	31 Aug 2020 03:47:38

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:47:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2cf0327a-83ec-4e60-ae41-951ed956532c' User entered '97.6'	System	31 Aug 2020 03:47:38
	System	31 Aug 2020 03:47:38

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:47:27', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2cf0327a-83ec-4e60-ae41-951ed956532c' User entered 'No (N)'	System	31 Aug 2020 03:47:38
	System	31 Aug 2020 03:47:38

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:47:36', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2cf0327a-83ec-4e60-ae41-951ed956532c' User entered '30 Aug 2020 22:47'	System	31 Aug 2020 03:47:38
	System	31 Aug 2020 03:47:38

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 5'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:10:41', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e159c27f-222a-43c1-bc8a-6a7a6ed0fe48' User entered 'Yes (Y)'	System	01 Sep 2020 00:11:01
	System	01 Sep 2020 00:11:01

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:10:50', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e159c27f-222a-43c1-bc8a-6a7a6ed0fe48'	System	01 Sep 2020 00:11:01
User entered '96.8'	System	01 Sep 2020 00:11:01

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:10:53', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e159c27f-222a-43c1-bc8a-6a7a6ed0fe48'	System	01 Sep 2020 00:11:01
User entered 'No (N)'	System	01 Sep 2020 00:11:01

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:10:59', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e159c27f-222a-43c1-bc8a-6a7a6ed0fe48'	System	01 Sep 2020 00:11:01
User entered '31 Aug 2020 19:10'	System	01 Sep 2020 00:11:01

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 6'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:44:07', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '6121c3b1-1ed5-459a-ab03-79ddf683e2ee' User entered 'Yes (Y)'	System	01 Sep 2020 23:44:37
	System	01 Sep 2020 23:44:37

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:44:27', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '6121c3b1-1ed5-459a-ab03-79ddf683e2ee' User entered '97.6'	System	01 Sep 2020 23:44:37
	System	01 Sep 2020 23:44:37

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:44:32', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '6121c3b1-1ed5-459a-ab03-79ddf683e2ee' User entered 'No (N)'	System	01 Sep 2020 23:44:37
	System	01 Sep 2020 23:44:37

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:44:35', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '6121c3b1-1ed5-459a-ab03-79ddf683e2ee' User entered '01 Sep 2020 18:44'	System	01 Sep 2020 23:44:37
	System	01 Sep 2020 23:44:37

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 7'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:55:38', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '05242bca-9abc-450b-8c02-afef7a007f26' User entered 'Yes (Y)'	System	03 Sep 2020 08:57:52
	System	03 Sep 2020 08:57:52

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:57:42', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '05242bca-9abc-450b-8c02-afef7a007f26' User entered '96.6'	System	03 Sep 2020 08:57:52
	System	03 Sep 2020 08:57:52

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:57:46', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '05242bca-9abc-450b-8c02-afef7a007f26'	System	03 Sep 2020 08:57:52
User entered 'No (N)'	System	03 Sep 2020 08:57:52

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:57:50', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '05242bca-9abc-450b-8c02-afef7a007f26' User entered '03 Sep 2020 03:57'	System	03 Sep 2020 08:57:52
	System	03 Sep 2020 08:57:52

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:24:54', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '7b56ee2e-fc9e-4461-99c9-16d88d82fd42'	System	27 Aug 2020 17:25:45
User entered 'None (1)'	System	27 Aug 2020 17:25:45

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:24:58', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '7b56ee2e-fc9e-4461-99c9-16d88d82fd42'	System	27 Aug 2020 17:25:45
User entered 'No (N)'	System	27 Aug 2020 17:25:45

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:25:04', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '7b56ee2e-fc9e-4461-99c9-16d88d82fd42'	System	27 Aug 2020 17:25:45
User entered 'No (N)'	System	27 Aug 2020 17:25:45

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:25:27', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '7b56ee2e-fc9e-4461-99c9-16d88d82fd42'	System	27 Aug 2020 17:25:45
User entered 'None (1)'	System	27 Aug 2020 17:25:45

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:25:41', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '7b56ee2e-fc9e-4461-99c9-16d88d82fd42'	System	27 Aug 2020 17:25:45
User entered '27 Aug 2020 12:25'	System	27 Aug 2020 17:25:45

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Aug 2020 12:13'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Aug 2020 14:43'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T10:37:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'cabb481f-e37e-4089-a323-309fb9eca505'	System	28 Aug 2020 15:37:41
User entered 'None (1)'	System	28 Aug 2020 15:37:41

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T10:37:26', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'cabb481f-e37e-4089-a323-309fb9eca505'	System	28 Aug 2020 15:37:41
User entered 'No (N)'	System	28 Aug 2020 15:37:41

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T10:37:29', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'cabb481f-e37e-4089-a323-309fb9eca505'	System	28 Aug 2020 15:37:41
User entered 'No (N)'	System	28 Aug 2020 15:37:41

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T10:37:33', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'cabb481f-e37e-4089-a323-309fb9eca505'	System	28 Aug 2020 15:37:41
User entered 'None (1)'	System	28 Aug 2020 15:37:41

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T10:37:39', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'cabb481f-e37e-4089-a323-309fb9eca505' User entered '28 Aug 2020 10:37'	System	28 Aug 2020 15:37:41
	System	28 Aug 2020 15:37:41

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Aug 2020 15:38'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 2'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:05:15', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9c9e696f-043f-489f-b08e-560855f69fa9'	System	28 Aug 2020 23:06:09
User entered 'None (1)'	System	28 Aug 2020 23:06:09

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:05:26', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9c9e696f-043f-489f-b08e-560855f69fa9'	System	28 Aug 2020 23:06:09
User entered 'No (N)'	System	28 Aug 2020 23:06:09

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:05:31', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9c9e696f-043f-489f-b08e-560855f69fa9'	System	28 Aug 2020 23:06:09
User entered 'No (N)'	System	28 Aug 2020 23:06:09

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:05:57', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9c9e696f-043f-489f-b08e-560855f69fa9'	System	28 Aug 2020 23:06:09
User entered 'None (1)'	System	28 Aug 2020 23:06:09

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:06:04', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9c9e696f-043f-489f-b08e-560855f69fa9' User entered '28 Aug 2020 18:06'	System	28 Aug 2020 23:06:09
	System	28 Aug 2020 23:06:09

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 3'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:54:42', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fcd2980-04cd-45cb-8e37-1508b84ceeb8'	System	30 Aug 2020 00:55:31
User entered 'None (1)'	System	30 Aug 2020 00:55:31

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:54:52', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fcd a2980-04cd-45cb-8e37-1508b84ceeb8' User entered 'No (N)'	System	30 Aug 2020 00:55:31
	System	30 Aug 2020 00:55:31

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:54:56', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fcd a2980-04cd-45cb-8e37-1508b84ceeb8' User entered 'No (N)'	System	30 Aug 2020 00:55:31
	System	30 Aug 2020 00:55:31

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:55:25', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fcd42980-04cd-45cb-8e37-1508b84ceeb8' User entered 'None (1)'	System	30 Aug 2020 00:55:31
	System	30 Aug 2020 00:55:31

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:55:28', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fcd a2980-04cd-45cb-8e37-1508b84ceeb8'	System	30 Aug 2020 00:55:31
User entered '29 Aug 2020 19:55'	System	30 Aug 2020 00:55:31

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 4'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:47:45', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '92942b1c-6b43-4a1a-a440-89fbaed4d2b2' User entered 'None (1)'	System	31 Aug 2020 03:48:03
	System	31 Aug 2020 03:48:03

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:47:49', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '92942b1c-6b43-4a1a-a440-89fbaed4d2b2' User entered 'No (N)'	System	31 Aug 2020 03:48:03
	System	31 Aug 2020 03:48:03

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:47:52', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '92942b1c-6b43-4a1a-a440-89fbaed4d2b2' User entered 'No (N)'	System	31 Aug 2020 03:48:03
	System	31 Aug 2020 03:48:03

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:47:56', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '92942b1c-6b43-4a1a-a440-89fbaed4d2b2' User entered 'None (1)'	System	31 Aug 2020 03:48:03
	System	31 Aug 2020 03:48:03

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:48:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '92942b1c-6b43-4a1a-a440-89fbaed4d2b2' User entered '30 Aug 2020 22:48'	System	31 Aug 2020 03:48:03
	System	31 Aug 2020 03:48:03

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 5'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:04', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e2590d83-3ce1-4c65-8ddc-05938a3d530a' User entered 'None (1)'	System	01 Sep 2020 00:11:24
	System	01 Sep 2020 00:11:24

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:07', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e2590d83-3ce1-4c65-8ddc-05938a3d530a' User entered 'No (N)'	System	01 Sep 2020 00:11:24
	System	01 Sep 2020 00:11:24

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:14', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e2590d83-3ce1-4c65-8ddc-05938a3d530a' User entered 'No (N)'	System	01 Sep 2020 00:11:24
	System	01 Sep 2020 00:11:24

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:18', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e2590d83-3ce1-4c65-8ddc-05938a3d530a' User entered 'None (1)'	System	01 Sep 2020 00:11:24
	System	01 Sep 2020 00:11:24

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:22', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e2590d83-3ce1-4c65-8ddc-05938a3d530a' User entered '31 Aug 2020 19:11'	System	01 Sep 2020 00:11:24
	System	01 Sep 2020 00:11:24

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 6'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:44:41', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd8fb9055-3376-47aa-8f76-d19d36821bfa'	System	01 Sep 2020 23:44:59
User entered 'None (1)'	System	01 Sep 2020 23:44:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:44:44', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd8fb9055-3376-47aa-8f76-d19d36821bfa' User entered 'No (N)'	System	01 Sep 2020 23:44:59
	System	01 Sep 2020 23:44:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:44:47', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd8fb9055-3376-47aa-8f76-d19d36821bfa' User entered 'No (N)'	System	01 Sep 2020 23:44:59
	System	01 Sep 2020 23:44:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:44:51', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd8fb9055-3376-47aa-8f76-d19d36821bfa'	System	01 Sep 2020 23:44:59
User entered 'None (1)'	System	01 Sep 2020 23:44:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:44:57', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd8fb9055-3376-47aa-8f76-d19d36821bfa' User entered '01 Sep 2020 18:44'	System	01 Sep 2020 23:44:59
	System	01 Sep 2020 23:44:59

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 7'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:57:54', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '7c5cb53b-a332-4dcd-8625-b2e14005bdd2'	System	03 Sep 2020 08:58:14
User entered 'None (1)'	System	03 Sep 2020 08:58:14

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:57:58', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '7c5cb53b-a332-4dcd-8625-b2e14005bdd2' User entered 'No (N)'	System	03 Sep 2020 08:58:14
	System	03 Sep 2020 08:58:14

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:01', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '7c5cb53b-a332-4dcd-8625-b2e14005bdd2' User entered 'No (N)'	System	03 Sep 2020 08:58:14
	System	03 Sep 2020 08:58:14

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:04', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '7c5cb53b-a332-4dcd-8625-b2e14005bdd2'	System	03 Sep 2020 08:58:14
User entered 'None (1)'	System	03 Sep 2020 08:58:14

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:12', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '7c5cb53b-a332-4dcd-8625-b2e14005bdd2' User entered '03 Sep 2020 03:58'	System	03 Sep 2020 08:58:14
	System	03 Sep 2020 08:58:14

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:25:50', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd021035f-d87d-4fc4-a122-bba82e9e7d7e' User entered 'None (0)'	System	27 Aug 2020 17:26:30
	System	27 Aug 2020 17:26:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:26:03', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd021035f-d87d-4fc4-a122-bba82e9e7d7e' User entered 'None (0)'	System	27 Aug 2020 17:26:30
	System	27 Aug 2020 17:26:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:26:09', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd021035f-d87d-4fc4-a122-bba82e9e7d7e' User entered 'None (0)'	System	27 Aug 2020 17:26:30
	System	27 Aug 2020 17:26:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:26:12', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd021035f-d87d-4fc4-a122-bba82e9e7d7e' User entered 'None (0)'	System	27 Aug 2020 17:26:30
	System	27 Aug 2020 17:26:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:26:14', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd021035f-d87d-4fc4-a122-bba82e9e7d7e' User entered 'None (0)'	System	27 Aug 2020 17:26:30
	System	27 Aug 2020 17:26:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:26:17', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd021035f-d87d-4fc4-a122-bba82e9e7d7e' User entered 'None (0)'	System	27 Aug 2020 17:26:30
	System	27 Aug 2020 17:26:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:26:20', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd021035f-d87d-4fc4-a122-bba82e9e7d7e' User entered 'No (N)'	System	27 Aug 2020 17:26:30
	System	27 Aug 2020 17:26:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T12:26:27', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd021035f-d87d-4fc4-a122-bba82e9e7d7e' User entered '27 Aug 2020 12:26'	System	27 Aug 2020 17:26:30
	System	27 Aug 2020 17:26:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Aug 2020 12:13'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Aug 2020 14:43'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:43:23', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4d517ae-6e47-4478-8159-ed6ba06046ac' User entered 'None (0)'	System	27 Aug 2020 23:43:56
	System	27 Aug 2020 23:43:56

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:43:26', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4d517ae-6e47-4478-8159-ed6ba06046ac' User entered 'None (0)'	System	27 Aug 2020 23:43:56
	System	27 Aug 2020 23:43:56

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:43:29', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4d517ae-6e47-4478-8159-ed6ba06046ac' User entered 'None (0)'	System	27 Aug 2020 23:43:56
	System	27 Aug 2020 23:43:56

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:43:32', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4d517ae-6e47-4478-8159-ed6ba06046ac' User entered 'None (0)'	System	27 Aug 2020 23:43:56
	System	27 Aug 2020 23:43:56

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:43:36', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4d517ae-6e47-4478-8159-ed6ba06046ac' User entered 'None (0)'	System	27 Aug 2020 23:43:56
	System	27 Aug 2020 23:43:56

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:43:39', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4d517ae-6e47-4478-8159-ed6ba06046ac' User entered 'None (0)'	System	27 Aug 2020 23:43:56
	System	27 Aug 2020 23:43:56

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:43:45', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4d517ae-6e47-4478-8159-ed6ba06046ac' User entered 'No (N)'	System	27 Aug 2020 23:43:56
	System	27 Aug 2020 23:43:56

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-27T18:43:53', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4d517ae-6e47-4478-8159-ed6ba06046ac' User entered '27 Aug 2020 18:43'	System	27 Aug 2020 23:43:56
	System	27 Aug 2020 23:43:56

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Aug 2020 15:38'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 2'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:06:09', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3025641c-2fa4-4c33-8f8d-385af914f138' User entered 'None (0)'	System	28 Aug 2020 23:06:47
	System	28 Aug 2020 23:06:47

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:06:12', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3025641c-2fa4-4c33-8f8d-385af914f138' User entered 'None (0)'	System	28 Aug 2020 23:06:47
	System	28 Aug 2020 23:06:47

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:06:16', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3025641c-2fa4-4c33-8f8d-385af914f138' User entered 'None (0)'	System	28 Aug 2020 23:06:47
	System	28 Aug 2020 23:06:47

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:06:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3025641c-2fa4-4c33-8f8d-385af914f138' User entered 'None (0)'	System	28 Aug 2020 23:06:47
	System	28 Aug 2020 23:06:47

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:06:24', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3025641c-2fa4-4c33-8f8d-385af914f138' User entered 'None (0)'	System	28 Aug 2020 23:06:47
	System	28 Aug 2020 23:06:47

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:06:27', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3025641c-2fa4-4c33-8f8d-385af914f138' User entered 'None (0)'	System	28 Aug 2020 23:06:47
	System	28 Aug 2020 23:06:47

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:06:36', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3025641c-2fa4-4c33-8f8d-385af914f138'	System	28 Aug 2020 23:06:47
User entered 'No (N)'	System	28 Aug 2020 23:06:47

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-28T18:06:46', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3025641c-2fa4-4c33-8f8d-385af914f138'	System	28 Aug 2020 23:06:47
User entered '28 Aug 2020 18:06'	System	28 Aug 2020 23:06:47

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 3'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:55:35', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4bc8707-a26b-4a89-af31-f02facf01d22'	System	30 Aug 2020 00:56:01
User entered 'None (0)'	System	30 Aug 2020 00:56:01

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:55:38', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4bc8707-a26b-4a89-af31-f02facf01d22'	System	30 Aug 2020 00:56:01
User entered 'None (0)'	System	30 Aug 2020 00:56:01

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:55:42', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4bc8707-a26b-4a89-af31-f02facf01d22'	System	30 Aug 2020 00:56:01
User entered 'None (0)'	System	30 Aug 2020 00:56:01

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:55:44', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4bc8707-a26b-4a89-af31-f02facf01d22'	System	30 Aug 2020 00:56:01
User entered 'None (0)'	System	30 Aug 2020 00:56:01

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:55:47', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4bc8707-a26b-4a89-af31-f02facf01d22'	System	30 Aug 2020 00:56:01
User entered 'None (0)'	System	30 Aug 2020 00:56:01

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:55:50', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4bc8707-a26b-4a89-af31-f02facf01d22'	System	30 Aug 2020 00:56:01
User entered 'None (0)'	System	30 Aug 2020 00:56:01

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:55:55', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4bc8707-a26b-4a89-af31-f02facf01d22'	System	30 Aug 2020 00:56:01
User entered 'No (N)'	System	30 Aug 2020 00:56:01

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-29T19:55:59', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4bc8707-a26b-4a89-af31-f02facf01d22'	System	30 Aug 2020 00:56:01
User entered '29 Aug 2020 19:55'	System	30 Aug 2020 00:56:01

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 4'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:48:04', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '507834bc-dce6-4155-b4e1-575773b18a94'	System	31 Aug 2020 03:48:35
User entered 'None (0)'	System	31 Aug 2020 03:48:35

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:48:07', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '507834bc-dce6-4155-b4e1-575773b18a94' User entered 'None (0)'	System	31 Aug 2020 03:48:35
	System	31 Aug 2020 03:48:35

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:48:10', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '507834bc-dce6-4155-b4e1-575773b18a94' User entered 'None (0)'	System	31 Aug 2020 03:48:35
	System	31 Aug 2020 03:48:35

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:48:13', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '507834bc-dce6-4155-b4e1-575773b18a94' User entered 'None (0)'	System	31 Aug 2020 03:48:35
	System	31 Aug 2020 03:48:35

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:48:15', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '507834bc-dce6-4155-b4e1-575773b18a94' User entered 'None (0)'	System	31 Aug 2020 03:48:35
	System	31 Aug 2020 03:48:35

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:48:18', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '507834bc-dce6-4155-b4e1-575773b18a94'	System	31 Aug 2020 03:48:35
User entered 'None (0)'	System	31 Aug 2020 03:48:35

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:48:23', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '507834bc-dce6-4155-b4e1-575773b18a94'	System	31 Aug 2020 03:48:35
User entered 'No (N)'	System	31 Aug 2020 03:48:35

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-30T22:48:30', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '507834bc-dce6-4155-b4e1-575773b18a94'	System	31 Aug 2020 03:48:35
User entered '30 Aug 2020 22:48'	System	31 Aug 2020 03:48:35

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 5'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:28', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe1234f9-709d-4f78-a27b-e88bf4f096bf' User entered 'None (0)'	System	01 Sep 2020 00:12:00
	System	01 Sep 2020 00:12:00

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:31', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe1234f9-709d-4f78-a27b-e88bf4f096bf' User entered 'None (0)'	System	01 Sep 2020 00:12:00
	System	01 Sep 2020 00:12:00

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:33', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe1234f9-709d-4f78-a27b-e88bf4f096bf' User entered 'None (0)'	System	01 Sep 2020 00:12:00
	System	01 Sep 2020 00:12:00

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:39', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe1234f9-709d-4f78-a27b-e88bf4f096bf' User entered 'None (0)'	System	01 Sep 2020 00:12:00
	System	01 Sep 2020 00:12:00

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:42', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe1234f9-709d-4f78-a27b-e88bf4f096bf' User entered 'None (0)'	System	01 Sep 2020 00:12:00
	System	01 Sep 2020 00:12:00

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:44', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe1234f9-709d-4f78-a27b-e88bf4f096bf' User entered 'None (0)'	System	01 Sep 2020 00:12:00
	System	01 Sep 2020 00:12:00

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:50', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe1234f9-709d-4f78-a27b-e88bf4f096bf' User entered 'No (N)'	System	01 Sep 2020 00:12:00
	System	01 Sep 2020 00:12:00

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-08-31T19:11:54', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe1234f9-709d-4f78-a27b-e88bf4f096bf' User entered '31 Aug 2020 19:11'	System	01 Sep 2020 00:12:00
	System	01 Sep 2020 00:12:00

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 6'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:45:01', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '99461d62-dc2d-4436-8b0c-2f1e1abec83b' User entered 'None (0)'	System	01 Sep 2020 23:45:23
	System	01 Sep 2020 23:45:23

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:45:03', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '99461d62-dc2d-4436-8b0c-2f1e1abec83b' User entered 'None (0)'	System	01 Sep 2020 23:45:23
	System	01 Sep 2020 23:45:23

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:45:05', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '99461d62-dc2d-4436-8b0c-2f1e1abec83b' User entered 'None (0)'	System	01 Sep 2020 23:45:23
	System	01 Sep 2020 23:45:23

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:45:08', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '99461d62-dc2d-4436-8b0c-2f1e1abec83b' User entered 'None (0)'	System	01 Sep 2020 23:45:23
	System	01 Sep 2020 23:45:23

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:45:11', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '99461d62-dc2d-4436-8b0c-2f1e1abec83b' User entered 'None (0)'	System	01 Sep 2020 23:45:23
	System	01 Sep 2020 23:45:23

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:45:13', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '99461d62-dc2d-4436-8b0c-2f1e1abec83b' User entered 'None (0)'	System	01 Sep 2020 23:45:23
	System	01 Sep 2020 23:45:23

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:45:19', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '99461d62-dc2d-4436-8b0c-2f1e1abec83b' User entered 'No (N)'	System	01 Sep 2020 23:45:23
	System	01 Sep 2020 23:45:23

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-01T18:45:22', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '99461d62-dc2d-4436-8b0c-2f1e1abec83b' User entered '01 Sep 2020 18:45'	System	01 Sep 2020 23:45:23
	System	01 Sep 2020 23:45:23

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 7'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:17', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'aee272ec-bc4e-4d27-9ba7-24ae13211097' User entered 'None (0)'	System	03 Sep 2020 08:58:50
	System	03 Sep 2020 08:58:50

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:20', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'aee272ec-bc4e-4d27-9ba7-24ae13211097' User entered 'None (0)'	System	03 Sep 2020 08:58:50
	System	03 Sep 2020 08:58:50

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:23', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'aee272ec-bc4e-4d27-9ba7-24ae13211097' User entered 'None (0)'	System	03 Sep 2020 08:58:50
	System	03 Sep 2020 08:58:50

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:29', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'aee272ec-bc4e-4d27-9ba7-24ae13211097' User entered 'None (0)'	System	03 Sep 2020 08:58:50
	System	03 Sep 2020 08:58:50

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:32', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'aee272ec-bc4e-4d27-9ba7-24ae13211097' User entered 'None (0)'	System	03 Sep 2020 08:58:50
	System	03 Sep 2020 08:58:50

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:34', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'aee272ec-bc4e-4d27-9ba7-24ae13211097' User entered 'None (0)'	System	03 Sep 2020 08:58:50
	System	03 Sep 2020 08:58:50

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:40', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'aee272ec-bc4e-4d27-9ba7-24ae13211097' User entered 'No (N)'	System	03 Sep 2020 08:58:50
	System	03 Sep 2020 08:58:50

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-03T03:58:47', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'aee272ec-bc4e-4d27-9ba7-24ae13211097' User entered '03 Sep 2020 03:58'	System	03 Sep 2020 08:58:50
	System	03 Sep 2020 08:58:50

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 16:58:30

US3312325

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:31:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Yes (Y)'	(b) (4)	04 Sep 2020 18:26:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312325

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:31:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '3 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:26:08

US3312325

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:31:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:26:08

US3312325

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:31:12
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:26:08

US3312325

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:31:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Yes (Y)'	(b) (4)	04 Sep 2020 18:26:11
	Karol Moore (b) (4)	
	(b) (4)	

US3312325

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'I'	System	04 Sep 2020 18:26:11

US3312325

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:49:56
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 19:56:40

US3312325

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:49:56
User entered '10 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 19:56:40

US3312325

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:49:56
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 19:56:40

US3312325

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:49:56
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 19:56:40

US3312325

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:18
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:49:59
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 19:56:45

US3312325

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:18
User entered 'I'	System	11 Sep 2020 19:56:45

US3312325

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:50:26
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	17 Sep 2020 19:29:57

US3312325

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:50:26
User entered '17 Sep 2020'	Monica Atwood (b) (4) (b) (4)	17 Sep 2020 19:29:57

US3312325

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:50:26
User entered 'Contact Made (CONTACT MADE)'	Monica Atwood (b) (4) (b) (4)	17 Sep 2020 19:29:57

US3312325

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:50:26
User entered empty.	Monica Atwood (b) (4) (b) (4)	17 Sep 2020 19:29:57

US3312325

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:50:30
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	17 Sep 2020 19:30:08

US3312325

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:05:22
User entered 'I'	System	17 Sep 2020 19:30:08

US3312325

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:51:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:13:42

US3312325

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:51:09
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:13:42

US3312325

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[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 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:51:09
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Sep 2020 16:13:42

US3312325

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'VISIT2'	System	24 Sep 2020 16:13:42

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '24 Sep 2020'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '10:08'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered '24 Sep 2020 10:08'	System	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '98.7' F	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '83'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'bpm'	System	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '14'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'breaths/min'	System	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '124'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'mmHg'	System	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '67'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'mmHg'	System	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '24 Sep 2020'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '11:41'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered '24 Sep 2020 11:41'	System	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '97.9' F	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '67'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'bpm'	System	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '14'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'breaths/min'	System	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:46
User entered '111'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'mmHg'	System	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User closed query 'Per CDM: Please indicate if PI considers diastolic blood pressure NCS or CS and report AE if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 12:02:33
Query 'Per CDM: Please indicate if PI considers diastolic blood pressure NCS or CS and report AE if necessary. Thank you' answered with 'Correct as entered NCS. Not an AE. Per protocol toxicity table, diastolic blood pressure not defined.' (Site from DM).	Heather Barker (b) (4) (b) (4)	21 Oct 2020 20:04:49
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:54:46
User opened query 'Per CDM: Please indicate if PI considers diastolic blood pressure NCS or CS and report AE if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 17:26:34
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 17:26:24
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS ENTERED. PER PROTOCOL TOXICITY TABLE DIASTOLIC BLOOD PRESSURE IS NOT DEFINED' (Site from System).	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:11
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		07 Oct 2020 15:19:59
User entered '59'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'mmHg'	System	07 Oct 2020 15:19:59

US3312325

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:51:49
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:21

US3312325

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:51:49
User entered '24 Sep 2020'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:21

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:14:12

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:03
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:14:12

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

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 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:03
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:14:12

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 16:14:12

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:03
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:14:12

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:03
User entered '11:10'	(b) (4), (b) (6)	24 Sep 2020 16:14:12

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered '24 Sep 2020 11:10'	System	24 Sep 2020 16:14:12

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:54:03
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	24 Sep 2020 16:14:12

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:54:03
User entered 'ONCE'	System	24 Sep 2020 16:14:12

US3312325

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 16:14:12

US3312325

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:52:19
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:40

US3312325

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:52:19
User entered '24 Sep 2020'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:40

US3312325

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:52:19
User entered '10:30'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:40

US3312325

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered '24 Sep 2020 10:30'	System	07 Oct 2020 15:20:40

US3312325

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:59:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:52:34
User entered '24 Sep 2020'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:58

US3312325

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:58

US3312325

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:53:39
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:58

US3312325

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:58:56
User closed query 'Per source nasopharyngeal swab collected at 10:26. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 18:02:59
Query 'Per source nasopharyngeal swab collected at 10:26. Please verify and update if needed. ' answered with 'updated per source' (Site from CRA).	Karol Moore (b) (4) (b) (4)	22 Oct 2020 14:38:58
User entered '10:26' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	22 Oct 2020 14:38:51
User opened query 'Per source nasopharyngeal swab collected at 10:26. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 19:53:38
User entered '10:30'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:58

US3312325

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered '24 Sep 2020 10:26'	System	22 Oct 2020 14:38:51
User entered '24 Sep 2020 10:30'	System	07 Oct 2020 15:20:58

US3312325

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:58

US3312325

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:58:56
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:58

US3312325

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:58:56
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:20:58

US3312325

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered empty.	System	07 Oct 2020 15:20:58

US3312325

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:55:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:14:43

US3312325

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'I'	System	24 Sep 2020 16:14:43

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:44:17', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '87a62897-0ae6-45d5-a199-722e272fc0cf' User entered 'Yes (Y)'	System	24 Sep 2020 16:44:43
	System	24 Sep 2020 16:44:43

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:44:23', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '87a62897-0ae6-45d5-a199-722e272fc0cf' User entered '97.9'	System	24 Sep 2020 16:44:43
	System	24 Sep 2020 16:44:43

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:44:30', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '87a62897-0ae6-45d5-a199-722e272fc0cf' User entered 'No (N)'	System	24 Sep 2020 16:44:43
	System	24 Sep 2020 16:44:43

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:44:40', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '87a62897-0ae6-45d5-a199-722e272fc0cf' User entered '24 Sep 2020 11:44'	System	24 Sep 2020 16:44:43
	System	24 Sep 2020 16:44:43

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '24 Sep 2020 11:30'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '24 Sep 2020 14:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:16:01', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e75060c0-5e28-4449-b923-d39298fa15db' User entered 'Yes (Y)'	System	25 Sep 2020 00:16:25
	System	25 Sep 2020 00:16:25

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:16:12', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e75060c0-5e28-4449-b923-d39298fa15db' User entered '98.2'	System	25 Sep 2020 00:16:25
	System	25 Sep 2020 00:16:25

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:16:16', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e75060c0-5e28-4449-b923-d39298fa15db' User entered 'No (N)'	System	25 Sep 2020 00:16:25
	System	25 Sep 2020 00:16:25

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:16:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e75060c0-5e28-4449-b923-d39298fa15db' User entered '24 Sep 2020 19:16'	System	25 Sep 2020 00:16:25
	System	25 Sep 2020 00:16:25

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '24 Sep 2020 14:55'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 2'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:46:34', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4b7ebb45-5198-47dd-a555-bbe4534ece4a' User entered 'Yes (Y)'	System	26 Sep 2020 00:46:53
	System	26 Sep 2020 00:46:53

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:46:42', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4b7ebb45-5198-47dd-a555-bbe4534ece4a' User entered '98.3'	System	26 Sep 2020 00:46:53
	System	26 Sep 2020 00:46:53

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:46:45', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4b7ebb45-5198-47dd-a555-bbe4534ece4a'	System	26 Sep 2020 00:46:53
User entered 'No (N)'	System	26 Sep 2020 00:46:53

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:46:49', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4b7ebb45-5198-47dd-a555-bbe4534ece4a' User entered '25 Sep 2020 19:46'	System	26 Sep 2020 00:46:53
	System	26 Sep 2020 00:46:53

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 3'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:11:23', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5805c330-0d65-47ef-93d9-58235f8bbb7d' User entered 'Yes (Y)'	System	27 Sep 2020 05:11:54
	System	27 Sep 2020 05:11:54

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:11:40', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5805c330-0d65-47ef-93d9-58235f8bbb7d' User entered '97.6'	System	27 Sep 2020 05:11:54
	System	27 Sep 2020 05:11:54

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:11:44', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5805c330-0d65-47ef-93d9-58235f8bbb7d' User entered 'No (N)'	System	27 Sep 2020 05:11:54
	System	27 Sep 2020 05:11:54

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:11:52', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5805c330-0d65-47ef-93d9-58235f8bbb7d' User entered '27 Sep 2020 00:11'	System	27 Sep 2020 05:11:54
	System	27 Sep 2020 05:11:54

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 4'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 5'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:25:04', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '53052b92-1a4f-461e-812b-c8f55dee5595' User entered 'Yes (Y)'	System	28 Sep 2020 17:25:25
	System	28 Sep 2020 17:25:25

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:25:14', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '53052b92-1a4f-461e-812b-c8f55dee5595' User entered '97.5'	System	28 Sep 2020 17:25:25
	System	28 Sep 2020 17:25:25

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:25:18', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '53052b92-1a4f-461e-812b-c8f55dee5595'	System	28 Sep 2020 17:25:25
User entered 'No (N)'	System	28 Sep 2020 17:25:25

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:25:22', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '53052b92-1a4f-461e-812b-c8f55dee5595' User entered '28 Sep 2020 12:25'	System	28 Sep 2020 17:25:25
	System	28 Sep 2020 17:25:25

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 6'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:12:12', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '83038a9d-a179-45d4-b546-db1b9b80e367'	System	30 Sep 2020 00:12:34
User entered 'Yes (Y)'	System	30 Sep 2020 00:12:34

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:12:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '83038a9d-a179-45d4-b546-db1b9b80e367' User entered '97.7'	System	30 Sep 2020 00:12:34
	System	30 Sep 2020 00:12:34

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:12:27', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '83038a9d-a179-45d4-b546-db1b9b80e367'	System	30 Sep 2020 00:12:34
User entered 'No (N)'	System	30 Sep 2020 00:12:34

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:12:31', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '83038a9d-a179-45d4-b546-db1b9b80e367'	System	30 Sep 2020 00:12:34
User entered '29 Sep 2020 19:12'	System	30 Sep 2020 00:12:34

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 7'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:52:56', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '0af09f30-7896-4312-805a-45f199879d03'	System	01 Oct 2020 03:53:39
User entered 'Yes (Y)'	System	01 Oct 2020 03:53:39

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:53:16', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '0af09f30-7896-4312-805a-45f199879d03' User entered '98.2'	System	01 Oct 2020 03:53:39
	System	01 Oct 2020 03:53:39

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:53:30', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '0af09f30-7896-4312-805a-45f199879d03'	System	01 Oct 2020 03:53:39
User entered 'No (N)'	System	01 Oct 2020 03:53:39

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:53:35', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '0af09f30-7896-4312-805a-45f199879d03' User entered '30 Sep 2020 22:53'	System	01 Oct 2020 03:53:39
	System	01 Oct 2020 03:53:39

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:44:50', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '50212ac2-ef5d-4060-9a76-f71bd8a89ecd' User entered 'None (1)'	System	24 Sep 2020 16:45:17
	System	24 Sep 2020 16:45:17

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:44:54', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '50212ac2-ef5d-4060-9a76-f71bd8a89ecd' User entered 'No (N)'	System	24 Sep 2020 16:45:17
	System	24 Sep 2020 16:45:17

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:44:59', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '50212ac2-ef5d-4060-9a76-f71bd8a89ecd' User entered 'No (N)'	System	24 Sep 2020 16:45:17
	System	24 Sep 2020 16:45:17

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:45:05', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '50212ac2-ef5d-4060-9a76-f71bd8a89ecd' User entered 'None (1)'	System	24 Sep 2020 16:45:17
	System	24 Sep 2020 16:45:17

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:45:11', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '50212ac2-ef5d-4060-9a76-f71bd8a89ecd' User entered '24 Sep 2020 11:45'	System	24 Sep 2020 16:45:17
	System	24 Sep 2020 16:45:17

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '24 Sep 2020 11:30'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '24 Sep 2020 14:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:16:38', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5d250977-8d50-4d65-a229-f6492db4873c' User entered 'None (1)'	System	25 Sep 2020 00:17:06
	System	25 Sep 2020 00:17:06

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:16:42', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5d250977-8d50-4d65-a229-f6492db4873c' User entered 'No (N)'	System	25 Sep 2020 00:17:06
	System	25 Sep 2020 00:17:06

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:16:51', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5d250977-8d50-4d65-a229-f6492db4873c' User entered 'No (N)'	System	25 Sep 2020 00:17:06
	System	25 Sep 2020 00:17:06

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:17:01', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5d250977-8d50-4d65-a229-f6492db4873c' User entered 'None (1)'	System	25 Sep 2020 00:17:06
	System	25 Sep 2020 00:17:06

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:17:05', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5d250977-8d50-4d65-a229-f6492db4873c' User entered '24 Sep 2020 19:17'	System	25 Sep 2020 00:17:06
	System	25 Sep 2020 00:17:06

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '24 Sep 2020 14:55'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 2'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:46:54', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '1d3c77c4-8ad2-459a-869f-5d7fda55a633'	System	26 Sep 2020 00:47:29
User entered 'None (1)'	System	26 Sep 2020 00:47:29

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:07', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '1d3c77c4-8ad2-459a-869f-5d7fda55a633'	System	26 Sep 2020 00:47:29
User entered 'No (N)'	System	26 Sep 2020 00:47:29

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:15', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '1d3c77c4-8ad2-459a-869f-5d7fda55a633'	System	26 Sep 2020 00:47:29
User entered 'No (N)'	System	26 Sep 2020 00:47:29

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:20', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '1d3c77c4-8ad2-459a-869f-5d7fda55a633'	System	26 Sep 2020 00:47:29
User entered 'None (1)'	System	26 Sep 2020 00:47:29

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:25', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '1d3c77c4-8ad2-459a-869f-5d7fda55a633'	System	26 Sep 2020 00:47:29
User entered '25 Sep 2020 19:47'	System	26 Sep 2020 00:47:29

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 3'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:03', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f9bd8c89-74af-4f62-b18d-d6a0384d9eda'	System	27 Sep 2020 05:12:21
User entered 'None (1)'	System	27 Sep 2020 05:12:21

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:07', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f9bd8c89-74af-4f62-b18d-d6a0384d9eda' User entered 'No (N)'	System	27 Sep 2020 05:12:21
	System	27 Sep 2020 05:12:21

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:11', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f9bd8c89-74af-4f62-b18d-d6a0384d9eda' User entered 'No (N)'	System	27 Sep 2020 05:12:21
	System	27 Sep 2020 05:12:21

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:15', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f9bd8c89-74af-4f62-b18d-d6a0384d9eda'	System	27 Sep 2020 05:12:21
User entered 'None (1)'	System	27 Sep 2020 05:12:21

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:19', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f9bd8c89-74af-4f62-b18d-d6a0384d9eda'	System	27 Sep 2020 05:12:21
User entered '27 Sep 2020 00:12'	System	27 Sep 2020 05:12:21

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 4'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 5'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:34:48', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'da9126b0-9e2e-4303-a575-d1ecb52dd8d1' User entered 'None (1)'	System	28 Sep 2020 17:35:10
	System	28 Sep 2020 17:35:10

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:34:53', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'da9126b0-9e2e-4303-a575-d1ecb52dd8d1' User entered 'No (N)'	System	28 Sep 2020 17:35:10
	System	28 Sep 2020 17:35:10

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:34:57', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'da9126b0-9e2e-4303-a575-d1ecb52dd8d1' User entered 'No (N)'	System	28 Sep 2020 17:35:10
	System	28 Sep 2020 17:35:10

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:35:02', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'da9126b0-9e2e-4303-a575-d1ecb52dd8d1'	System	28 Sep 2020 17:35:10
User entered 'None (1)'	System	28 Sep 2020 17:35:10

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:35:09', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'da9126b0-9e2e-4303-a575-d1ecb52dd8d1' User entered '28 Sep 2020 12:35'	System	28 Sep 2020 17:35:10
	System	28 Sep 2020 17:35:10

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 6'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:12:36', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4f9c4eb5-b9f1-4fa2-a0ac-96fd6569e03f' User entered 'None (1)'	System	30 Sep 2020 00:13:11
	System	30 Sep 2020 00:13:11

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:12:40', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4f9c4eb5-b9f1-4fa2-a0ac-96fd6569e03f' User entered 'No (N)'	System	30 Sep 2020 00:13:11
	System	30 Sep 2020 00:13:11

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:12:43', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4f9c4eb5-b9f1-4fa2-a0ac-96fd6569e03f' User entered 'No (N)'	System	30 Sep 2020 00:13:11
	System	30 Sep 2020 00:13:11

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:12:46', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4f9c4eb5-b9f1-4fa2-a0ac-96fd6569e03f' User entered 'None (1)'	System	30 Sep 2020 00:13:11
	System	30 Sep 2020 00:13:11

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:13:07', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4f9c4eb5-b9f1-4fa2-a0ac-96fd6569e03f' User entered '29 Sep 2020 19:13'	System	30 Sep 2020 00:13:11
	System	30 Sep 2020 00:13:11

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 7'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:53:41', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'a357b85b-cd4a-47b8-96df-1aaa0e1731a1' User entered 'None (1)'	System	01 Oct 2020 03:54:00
	System	01 Oct 2020 03:54:00

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:53:45', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'a357b85b-cd4a-47b8-96df-1aaa0e1731a1' User entered 'No (N)'	System	01 Oct 2020 03:54:00
	System	01 Oct 2020 03:54:00

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:53:48', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'a357b85b-cd4a-47b8-96df-1aaa0e1731a1' User entered 'No (N)'	System	01 Oct 2020 03:54:00
	System	01 Oct 2020 03:54:00

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:53:52', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'a357b85b-cd4a-47b8-96df-1aaa0e1731a1' User entered 'None (1)'	System	01 Oct 2020 03:54:00
	System	01 Oct 2020 03:54:00

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:53:58', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'a357b85b-cd4a-47b8-96df-1aaa0e1731a1' User entered '30 Sep 2020 22:53'	System	01 Oct 2020 03:54:00
	System	01 Oct 2020 03:54:00

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:45:16', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e9200488-6df0-486e-a5a8-213cc237c46b' User entered 'None (0)'	System	24 Sep 2020 16:45:41
	System	24 Sep 2020 16:45:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:45:19', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e9200488-6df0-486e-a5a8-213cc237c46b' User entered 'None (0)'	System	24 Sep 2020 16:45:41
	System	24 Sep 2020 16:45:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:45:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e9200488-6df0-486e-a5a8-213cc237c46b' User entered 'None (0)'	System	24 Sep 2020 16:45:41
	System	24 Sep 2020 16:45:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:45:24', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e9200488-6df0-486e-a5a8-213cc237c46b' User entered 'None (0)'	System	24 Sep 2020 16:45:41
	System	24 Sep 2020 16:45:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:45:27', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e9200488-6df0-486e-a5a8-213cc237c46b' User entered 'None (0)'	System	24 Sep 2020 16:45:41
	System	24 Sep 2020 16:45:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:45:29', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e9200488-6df0-486e-a5a8-213cc237c46b' User entered 'None (0)'	System	24 Sep 2020 16:45:41
	System	24 Sep 2020 16:45:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:45:33', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e9200488-6df0-486e-a5a8-213cc237c46b' User entered 'No (N)'	System	24 Sep 2020 16:45:41
	System	24 Sep 2020 16:45:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T11:45:38', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e9200488-6df0-486e-a5a8-213cc237c46b' User entered '24 Sep 2020 11:45'	System	24 Sep 2020 16:45:41
	System	24 Sep 2020 16:45:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '24 Sep 2020 11:30'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '24 Sep 2020 14:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:17:09', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3f6666bb-2f26-415a-82ae-146abb1d5f27' User entered 'None (0)'	System	25 Sep 2020 00:17:37
	System	25 Sep 2020 00:17:37

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:17:12', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3f6666bb-2f26-415a-82ae-146abb1d5f27' User entered 'None (0)'	System	25 Sep 2020 00:17:37
	System	25 Sep 2020 00:17:37

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:17:14', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3f6666bb-2f26-415a-82ae-146abb1d5f27' User entered 'None (0)'	System	25 Sep 2020 00:17:37
	System	25 Sep 2020 00:17:37

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:17:17', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3f6666bb-2f26-415a-82ae-146abb1d5f27' User entered 'None (0)'	System	25 Sep 2020 00:17:37
	System	25 Sep 2020 00:17:37

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:17:19', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3f6666bb-2f26-415a-82ae-146abb1d5f27' User entered 'None (0)'	System	25 Sep 2020 00:17:37
	System	25 Sep 2020 00:17:37

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:17:22', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3f6666bb-2f26-415a-82ae-146abb1d5f27' User entered 'None (0)'	System	25 Sep 2020 00:17:37
	System	25 Sep 2020 00:17:37

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:17:27', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3f6666bb-2f26-415a-82ae-146abb1d5f27' User entered 'No (N)'	System	25 Sep 2020 00:17:37
	System	25 Sep 2020 00:17:37

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-24T19:17:32', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '3f6666bb-2f26-415a-82ae-146abb1d5f27'	System	25 Sep 2020 00:17:37
User entered '24 Sep 2020 19:17'	System	25 Sep 2020 00:17:37

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '24 Sep 2020 14:55'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 2'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:29', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4356475d-a9d9-40db-ae66-eb250f153c9e' User entered 'None (0)'	System	26 Sep 2020 00:47:59
	System	26 Sep 2020 00:47:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:32', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4356475d-a9d9-40db-ae66-eb250f153c9e' User entered 'None (0)'	System	26 Sep 2020 00:47:59
	System	26 Sep 2020 00:47:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:34', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4356475d-a9d9-40db-ae66-eb250f153c9e' User entered 'None (0)'	System	26 Sep 2020 00:47:59
	System	26 Sep 2020 00:47:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:37', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4356475d-a9d9-40db-ae66-eb250f153c9e' User entered 'None (0)'	System	26 Sep 2020 00:47:59
	System	26 Sep 2020 00:47:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:39', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4356475d-a9d9-40db-ae66-eb250f153c9e' User entered 'None (0)'	System	26 Sep 2020 00:47:59
	System	26 Sep 2020 00:47:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:42', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4356475d-a9d9-40db-ae66-eb250f153c9e' User entered 'None (0)'	System	26 Sep 2020 00:47:59
	System	26 Sep 2020 00:47:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:49', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4356475d-a9d9-40db-ae66-eb250f153c9e' User entered 'No (N)'	System	26 Sep 2020 00:47:59
	System	26 Sep 2020 00:47:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-25T19:47:52', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4356475d-a9d9-40db-ae66-eb250f153c9e' User entered '25 Sep 2020 19:47'	System	26 Sep 2020 00:47:59
	System	26 Sep 2020 00:47:59

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 3'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:24', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '587f0470-83f7-4e0f-989d-3104eb3431ef' User entered 'None (0)'	System	27 Sep 2020 05:13:02
	System	27 Sep 2020 05:13:02

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:27', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '587f0470-83f7-4e0f-989d-3104eb3431ef' User entered 'None (0)'	System	27 Sep 2020 05:13:02
	System	27 Sep 2020 05:13:02

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:31', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '587f0470-83f7-4e0f-989d-3104eb3431ef' User entered 'None (0)'	System	27 Sep 2020 05:13:02
	System	27 Sep 2020 05:13:02

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:34', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '587f0470-83f7-4e0f-989d-3104eb3431ef' User entered 'None (0)'	System	27 Sep 2020 05:13:02
	System	27 Sep 2020 05:13:02

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:37', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '587f0470-83f7-4e0f-989d-3104eb3431ef' User entered 'None (0)'	System	27 Sep 2020 05:13:02
	System	27 Sep 2020 05:13:02

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:40', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '587f0470-83f7-4e0f-989d-3104eb3431ef' User entered 'None (0)'	System	27 Sep 2020 05:13:02
	System	27 Sep 2020 05:13:02

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:45', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '587f0470-83f7-4e0f-989d-3104eb3431ef' User entered 'No (N)'	System	27 Sep 2020 05:13:02
	System	27 Sep 2020 05:13:02

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-27T00:12:57', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '587f0470-83f7-4e0f-989d-3104eb3431ef' User entered '27 Sep 2020 00:12'	System	27 Sep 2020 05:13:02
	System	27 Sep 2020 05:13:02

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 4'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 5'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:35:13', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '47dd2936-131b-44fb-b94c-b94c80a98071' User entered 'None (0)'	System	28 Sep 2020 17:35:36
	System	28 Sep 2020 17:35:36

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:35:15', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '47dd2936-131b-44fb-b94c-b94c80a98071' User entered 'None (0)'	System	28 Sep 2020 17:35:36
	System	28 Sep 2020 17:35:36

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:35:18', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '47dd2936-131b-44fb-b94c-b94c80a98071' User entered 'None (0)'	System	28 Sep 2020 17:35:36
	System	28 Sep 2020 17:35:36

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:35:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '47dd2936-131b-44fb-b94c-b94c80a98071' User entered 'None (0)'	System	28 Sep 2020 17:35:36
	System	28 Sep 2020 17:35:36

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:35:23', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '47dd2936-131b-44fb-b94c-b94c80a98071' User entered 'None (0)'	System	28 Sep 2020 17:35:36
	System	28 Sep 2020 17:35:36

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:35:25', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '47dd2936-131b-44fb-b94c-b94c80a98071' User entered 'None (0)'	System	28 Sep 2020 17:35:36
	System	28 Sep 2020 17:35:36

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:35:29', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '47dd2936-131b-44fb-b94c-b94c80a98071' User entered 'No (N)'	System	28 Sep 2020 17:35:36
	System	28 Sep 2020 17:35:36

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-28T12:35:33', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '47dd2936-131b-44fb-b94c-b94c80a98071' User entered '28 Sep 2020 12:35'	System	28 Sep 2020 17:35:36
	System	28 Sep 2020 17:35:36

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 6'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:13:11', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b04f73ad-d822-4c04-9f29-f4e7bd953f9d' User entered 'None (0)'	System	30 Sep 2020 00:13:41
	System	30 Sep 2020 00:13:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:13:14', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b04f73ad-d822-4c04-9f29-f4e7bd953f9d' User entered 'None (0)'	System	30 Sep 2020 00:13:41
	System	30 Sep 2020 00:13:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:13:17', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b04f73ad-d822-4c04-9f29-f4e7bd953f9d' User entered 'None (0)'	System	30 Sep 2020 00:13:41
	System	30 Sep 2020 00:13:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:13:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b04f73ad-d822-4c04-9f29-f4e7bd953f9d' User entered 'None (0)'	System	30 Sep 2020 00:13:41
	System	30 Sep 2020 00:13:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:13:24', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b04f73ad-d822-4c04-9f29-f4e7bd953f9d' User entered 'None (0)'	System	30 Sep 2020 00:13:41
	System	30 Sep 2020 00:13:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:13:26', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b04f73ad-d822-4c04-9f29-f4e7bd953f9d' User entered 'None (0)'	System	30 Sep 2020 00:13:41
	System	30 Sep 2020 00:13:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:13:32', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b04f73ad-d822-4c04-9f29-f4e7bd953f9d' User entered 'No (N)'	System	30 Sep 2020 00:13:41
	System	30 Sep 2020 00:13:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-29T19:13:38', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'b04f73ad-d822-4c04-9f29-f4e7bd953f9d' User entered '29 Sep 2020 19:13'	System	30 Sep 2020 00:13:41
	System	30 Sep 2020 00:13:41

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	24 Sep 2020 16:14:12
User entered 'Day 7'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:54:03', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '422f7713-8d66-4ace-b3a8-fd8c48072ee3' User entered 'None (0)'	System	01 Oct 2020 03:54:28
	System	01 Oct 2020 03:54:28

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:54:05', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '422f7713-8d66-4ace-b3a8-fd8c48072ee3' User entered 'None (0)'	System	01 Oct 2020 03:54:28
	System	01 Oct 2020 03:54:28

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:54:08', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '422f7713-8d66-4ace-b3a8-fd8c48072ee3' User entered 'None (0)'	System	01 Oct 2020 03:54:28
	System	01 Oct 2020 03:54:28

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:54:11', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '422f7713-8d66-4ace-b3a8-fd8c48072ee3' User entered 'None (0)'	System	01 Oct 2020 03:54:28
	System	01 Oct 2020 03:54:28

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:54:13', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '422f7713-8d66-4ace-b3a8-fd8c48072ee3' User entered 'None (0)'	System	01 Oct 2020 03:54:28
	System	01 Oct 2020 03:54:28

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:54:16', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '422f7713-8d66-4ace-b3a8-fd8c48072ee3' User entered 'None (0)'	System	01 Oct 2020 03:54:28
	System	01 Oct 2020 03:54:28

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:54:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '422f7713-8d66-4ace-b3a8-fd8c48072ee3' User entered 'No (N)'	System	01 Oct 2020 03:54:28
	System	01 Oct 2020 03:54:28

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-09-30T22:54:24', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '422f7713-8d66-4ace-b3a8-fd8c48072ee3' User entered '30 Sep 2020 22:54'	System	01 Oct 2020 03:54:28
	System	01 Oct 2020 03:54:28

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:14:12

US3312325

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:59:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:14:12

US3312325

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:59:07
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:21:45

US3312325

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:59:07
User entered '01 Oct 2020'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:21:45

US3312325

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:59:07
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:21:45

US3312325

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:59:07
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:21:45

US3312325

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:59:19
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 15:22:01

US3312325

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'I'	System	07 Oct 2020 15:22:01

US3312325

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:00:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:15:30

US3312325

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:00:09
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Oct 2020 22:16:49
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	08 Oct 2020 22:16:49
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 22:16:49
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Oct 2020 22:15:30
User entered '1 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 22:15:30

US3312325

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:00:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 22:15:30

US3312325

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:00:09
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:15:30

US3312325

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:00:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:16:56

US3312325

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'I'	System	08 Oct 2020 22:16:56

US3312325

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:00:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 13:44:14

US3312325

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:00:34
User entered '15 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 13:44:14

US3312325

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:00:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Oct 2020 13:44:14

US3312325

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:00:34
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 13:44:14

US3312325

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:00:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 13:44:17

US3312325

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'I'	System	16 Oct 2020 13:44:17

US3312325

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:13:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:20

US3312325

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:13:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:20

US3312325

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[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 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:13:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:20

US3312325

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'VISIT3'	System	29 Oct 2020 15:29:20

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:26
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:26
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:26
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '10:15'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered '22 Oct 2020 10:15'	System	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:26
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:26
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:26
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:26
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '71'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'bpm'	System	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:26
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '16'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'breaths/min'	System	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:26
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '106'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'mmHg'	System	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:26
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '60'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'mmHg'	System	29 Oct 2020 15:29:39

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59

US3312325

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59

US3312325

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:43

US3312325

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:14:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:43

US3312325

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:15:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:53

US3312325

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:15:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:53

US3312325

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:15:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered '10:20'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:53

US3312325

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered '22 Oct 2020 10:20'	System	29 Oct 2020 15:29:53

US3312325

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:15:55
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:38:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 15:29:56

US3312325

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered '1'	System	29 Oct 2020 15:29:56

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 64'	System	27 Aug 2020 16:58:30

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-10-29T15:45:25', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'db672381-797e-462c-83b9-a742f369cdc2'	System	29 Oct 2020 20:45:49
User entered 'No (N)'	System	29 Oct 2020 20:45:49

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-10-29T15:45:30', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'db672381-797e-462c-83b9-a742f369cdc2'	System	29 Oct 2020 20:45:49
User entered 'No (N)'	System	29 Oct 2020 20:45:49

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-10-29T15:45:41', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'db672381-797e-462c-83b9-a742f369cdc2' User entered '29 Oct 2020 15:45:41'	System	29 Oct 2020 20:45:49
	System	29 Oct 2020 20:45:49

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 16:58:30

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 71'	System	27 Aug 2020 16:58:30

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-05T12:37:16', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4dd4b91-4d0d-460c-924e-6fd9b9ca636f' User entered 'Yes (Y)'	System	05 Nov 2020 18:38:22
	System	05 Nov 2020 18:38:22

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-05T12:37:05', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4dd4b91-4d0d-460c-924e-6fd9b9ca636f' User entered 'No (N)'	System	05 Nov 2020 18:38:22
	System	05 Nov 2020 18:38:22

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-05T12:37:29', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4dd4b91-4d0d-460c-924e-6fd9b9ca636f' User entered 'No (N)'	System	05 Nov 2020 18:38:22
	System	05 Nov 2020 18:38:22

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-05T12:37:39', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4dd4b91-4d0d-460c-924e-6fd9b9ca636f'	System	05 Nov 2020 18:38:22
User entered 'Yes (Y)'	System	05 Nov 2020 18:38:22

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Please 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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-05T12:37:54', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4dd4b91-4d0d-460c-924e-6fd9b9ca636f'	System	05 Nov 2020 18:38:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Nov 2020 18:38:22

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-05T12:38:12', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e4dd4b91-4d0d-460c-924e-6fd9b9ca636f' User entered '05 Nov 2020 12:38:12'	System	05 Nov 2020 18:38:22
	System	05 Nov 2020 18:38:22

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 16:58:30

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered 'Day 78'	System	27 Aug 2020 16:58:30

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-11T23:37:35', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '232909a1-33eb-4e9a-ae06-4185572fd556'	System	12 Nov 2020 05:37:47
User entered 'No (N)'	System	12 Nov 2020 05:37:47

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-11T23:37:40', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '232909a1-33eb-4e9a-ae06-4185572fd556'	System	12 Nov 2020 05:37:47
User entered 'No (N)'	System	12 Nov 2020 05:37:47

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-11T23:37:45', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '232909a1-33eb-4e9a-ae06-4185572fd556' User entered '11 Nov 2020 23:37:45'	System	12 Nov 2020 05:37:47
	System	12 Nov 2020 05:37:47

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 16:58:30

US3312325

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:32:35
Data entry locked.	System	27 Aug 2020 16:58:30
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 16:58:30

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-25T17:20:23', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2cc89f9b-a1bc-4e34-96b9-177df9c842d3' User entered 'No (N)'	System	25 Nov 2020 23:20:37

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-25T17:20:29', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2cc89f9b-a1bc-4e34-96b9-177df9c842d3' User entered 'No (N)'	System	25 Nov 2020 23:20:37

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-25T17:20:34', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '2cc89f9b-a1bc-4e34-96b9-177df9c842d3' User entered '25 Nov 2020 17:20:34'	System	25 Nov 2020 23:20:37
	System	25 Nov 2020 23:20:37

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-30T19:29:20', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe39087b-e07c-46d1-b81f-b2ede871ca38'	System	01 Dec 2020 01:29:35
User entered 'No (N)'	System	01 Dec 2020 01:29:35

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-30T19:29:24', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe39087b-e07c-46d1-b81f-b2ede871ca38'	System	01 Dec 2020 01:29:35
User entered 'No (N)'	System	01 Dec 2020 01:29:35

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-11-30T19:29:32', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'fe39087b-e07c-46d1-b81f-b2ede871ca38' User entered '30 Nov 2020 19:29:32'	System	01 Dec 2020 01:29:35
	System	01 Dec 2020 01:29:35

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-08T17:59:51', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '37883087-af81-450a-a5f9-ca93106cfea8' User entered 'No (N)'	System	09 Dec 2020 00:00:09
	System	09 Dec 2020 00:00:09

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-08T17:59:57', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '37883087-af81-450a-a5f9-ca93106cfea8' User entered 'No (N)'	System	09 Dec 2020 00:00:09
	System	09 Dec 2020 00:00:09

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-08T18:00:01', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '37883087-af81-450a-a5f9-ca93106cfea8' User entered '08 Dec 2020 18:00:01'	System	09 Dec 2020 00:00:09
	System	09 Dec 2020 00:00:09

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-15T19:49:48', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '623a5e6b-7908-45ad-8c89-19461c2bc15a' User entered 'No (N)'	System	16 Dec 2020 01:51:06
	System	16 Dec 2020 01:51:06

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-15T19:50:04', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '623a5e6b-7908-45ad-8c89-19461c2bc15a' User entered 'Yes (Y)'	System	16 Dec 2020 01:51:06
	System	16 Dec 2020 01:51:06

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Please 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-15T19:50:35', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '623a5e6b-7908-45ad-8c89-19461c2bc15a'	System	16 Dec 2020 01:51:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 01:51:06

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-15T19:50:53', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '623a5e6b-7908-45ad-8c89-19461c2bc15a' User entered '15 Dec 2020 19:50:53'	System	16 Dec 2020 01:51:06
	System	16 Dec 2020 01:51:06

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-22T15:55:47', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4b338c8-4104-4e86-9e8d-dd3e33acc5bf' User entered 'No (N)'	System	22 Dec 2020 21:56:03
	System	22 Dec 2020 21:56:03

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-22T15:55:51', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4b338c8-4104-4e86-9e8d-dd3e33acc5bf' User entered 'No (N)'	System	22 Dec 2020 21:56:03

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-22T15:56:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'f4b338c8-4104-4e86-9e8d-dd3e33acc5bf' User entered '22 Dec 2020 15:56:00'	System	22 Dec 2020 21:56:03
	System	22 Dec 2020 21:56:03

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-29T14:32:01', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '82e4a10d-b65a-4877-8341-220ec9b2dfb6' User entered 'No (N)'	System	29 Dec 2020 20:32:14
	System	29 Dec 2020 20:32:14

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-29T14:32:04', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '82e4a10d-b65a-4877-8341-220ec9b2dfb6' User entered 'No (N)'	System	29 Dec 2020 20:32:14
	System	29 Dec 2020 20:32:14

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2020-12-29T14:32:09', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '82e4a10d-b65a-4877-8341-220ec9b2dfb6' User entered '29 Dec 2020 14:32:09'	System	29 Dec 2020 20:32:14
	System	29 Dec 2020 20:32:14

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-04T12:01:10', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '509f5f2a-72f3-4ac3-9934-376e7498d05b'	System	04 Jan 2021 18:01:24
User entered 'No (N)'	System	04 Jan 2021 18:01:24

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-04T12:01:13', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '509f5f2a-72f3-4ac3-9934-376e7498d05b'	System	04 Jan 2021 18:01:24
User entered 'No (N)'	System	04 Jan 2021 18:01:24

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-04T12:01:20', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '509f5f2a-72f3-4ac3-9934-376e7498d05b' User entered '04 Jan 2021 12:01:20'	System	04 Jan 2021 18:01:24
	System	04 Jan 2021 18:01:24

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-11T22:00:38', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'cd1877c5-e6c9-4c95-a18b-f672be79643e' User entered 'No (N)'	System	13 Jan 2021 16:01:06
	System	13 Jan 2021 16:01:06

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-11T22:00:44', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'cd1877c5-e6c9-4c95-a18b-f672be79643e' User entered 'No (N)'	System	13 Jan 2021 16:01:06

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-11T22:00:55', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'cd1877c5-e6c9-4c95-a18b-f672be79643e' User entered '11 Jan 2021 22:00:55'	System	13 Jan 2021 16:01:06
	System	13 Jan 2021 16:01:06

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-17T09:55:53', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'c8c33268-cc55-472a-be46-9dd6ed2bab37' User entered 'No (N)'	System	17 Jan 2021 15:56:11
	System	17 Jan 2021 15:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-17T09:55:58', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'c8c33268-cc55-472a-be46-9dd6ed2bab37' User entered 'No (N)'	System	17 Jan 2021 15:56:11
	System	17 Jan 2021 15:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-17T09:56:08', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'c8c33268-cc55-472a-be46-9dd6ed2bab37' User entered '17 Jan 2021 09:56:08'	System	17 Jan 2021 15:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-25T12:30:04', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'ea1f585d-7f34-49f2-bcd1-aa1ce8dabfc9' User entered 'No (N)'	System	25 Jan 2021 18:30:24
	System	25 Jan 2021 18:30:24

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-25T12:30:09', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'ea1f585d-7f34-49f2-bcd1-aa1ce8dabfc9' User entered 'No (N)'	System	25 Jan 2021 18:30:24

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-01-25T12:30:21', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'ea1f585d-7f34-49f2-bcd1-aa1ce8dabfc9' User entered '25 Jan 2021 12:30:21'	System	25 Jan 2021 18:30:24
	System	25 Jan 2021 18:30:24

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-02T07:54:30', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9b6841b8-f1ee-47c4-a714-6e252e898a2e' User entered 'No (N)'	System	02 Feb 2021 13:54:41
	System	02 Feb 2021 13:54:41

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-02T07:54:34', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9b6841b8-f1ee-47c4-a714-6e252e898a2e' User entered 'No (N)'	System	02 Feb 2021 13:54:41
	System	02 Feb 2021 13:54:41

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-02T07:54:39', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9b6841b8-f1ee-47c4-a714-6e252e898a2e' User entered '02 Feb 2021 07:54:39'	System	02 Feb 2021 13:54:41
	System	02 Feb 2021 13:54:41

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-08T13:11:48', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '82c487c9-3631-49cc-b452-faceb555f336' User entered 'No (N)'	System	09 Feb 2021 17:26:25
	System	09 Feb 2021 17:26:25

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-08T13:11:52', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '82c487c9-3631-49cc-b452-faceb555f336'	System	09 Feb 2021 17:26:25
User entered 'No (N)'	System	09 Feb 2021 17:26:25

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-08T13:11:58', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '82c487c9-3631-49cc-b452-faceb555f336'	System	09 Feb 2021 17:26:25
User entered '08 Feb 2021 13:11:58'	System	09 Feb 2021 17:26:25

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-15T20:25:36', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd9b93d3a-f15a-44aa-bfbb-fa292805c1c0'	System	16 Feb 2021 02:32:01
User entered 'No (N)'	System	16 Feb 2021 02:32:01

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-15T20:25:39', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd9b93d3a-f15a-44aa-bfbb-fa292805c1c0' User entered 'No (N)'	System	16 Feb 2021 02:32:01
	System	16 Feb 2021 02:32:01

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-15T20:25:44', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd9b93d3a-f15a-44aa-bfbb-fa292805c1c0' User entered '15 Feb 2021 20:25:44'	System	16 Feb 2021 02:32:01

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-22T12:16:20', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '73b97798-649c-4656-aa49-4a1600fe88c0' User entered 'No (N)'	System	22 Feb 2021 18:19:18
	System	22 Feb 2021 18:19:18

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-22T12:16:35', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '73b97798-649c-4656-aa49-4a1600fe88c0' User entered 'No (N)'	System	22 Feb 2021 18:19:18
	System	22 Feb 2021 18:19:18

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-02-22T12:16:48', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '73b97798-649c-4656-aa49-4a1600fe88c0' User entered '22 Feb 2021 12:16:48'	System	22 Feb 2021 18:19:18
	System	22 Feb 2021 18:19:18

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-01T12:11:57-06:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '81b49726-2f53-4a94-8ed8-c576cfde360d'	System	01 Mar 2021 18:18:41
User entered 'No (N)'	System	01 Mar 2021 18:18:41

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-01T12:12:02-06:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '81b49726-2f53-4a94-8ed8-c576cfde360d' User entered 'No (N)'	System	01 Mar 2021 18:18:41
	System	01 Mar 2021 18:18:41

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-01T12:12:09-06:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '81b49726-2f53-4a94-8ed8-c576cfde360d'	System	01 Mar 2021 18:18:41
User entered '01 Mar 2021 18:12:09'	System	01 Mar 2021 18:18:41

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-08T20:01:58-06:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e3ed02ec-90a0-4211-b100-0451b9e758c2'	System	09 Mar 2021 02:10:23
User entered 'No (N)'	System	09 Mar 2021 02:10:23

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-08T20:02:03-06:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e3ed02ec-90a0-4211-b100-0451b9e758c2'	System	09 Mar 2021 02:10:23
User entered 'No (N)'	System	09 Mar 2021 02:10:23

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-08T20:02:07-06:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'e3ed02ec-90a0-4211-b100-0451b9e758c2' User entered '08 Mar 2021 20:02:07'	System	09 Mar 2021 02:10:23
	System	09 Mar 2021 02:10:23

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-15T22:06:53-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '6e90a3b3-641c-4f9b-b426-5c5711760562' User entered 'No (N)'	System	16 Mar 2021 03:07:11
	System	16 Mar 2021 03:07:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-15T22:06:59-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '6e90a3b3-641c-4f9b-b426-5c5711760562' User entered 'No (N)'	System	16 Mar 2021 03:07:11
	System	16 Mar 2021 03:07:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-15T22:07:04-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '6e90a3b3-641c-4f9b-b426-5c5711760562' User entered '15 Mar 2021 22:07:04'	System	16 Mar 2021 03:07:11
	System	16 Mar 2021 03:07:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-22T20:24:00-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'eachb0469-cfc9-4d32-ad45-db08bfa0e0f5'	System	23 Mar 2021 01:24:40
User entered 'No (N)'	System	23 Mar 2021 01:24:40

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-22T20:24:03-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'each0469-cfc9-4d32-ad45-db08bfa0e0f5'	System	23 Mar 2021 01:24:40
User entered 'No (N)'	System	23 Mar 2021 01:24:40

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-22T20:24:07-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'each0469-cfc9-4d32-ad45-db08bfa0e0f5'	System	23 Mar 2021 01:24:40
User entered '22 Mar 2021 20:24:07'	System	23 Mar 2021 01:24:40

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-29T16:19:57-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '520f1b86-ad50-4b78-8bde-aece08cb7b17'	System	29 Mar 2021 21:20:11
User entered 'No (N)'	System	29 Mar 2021 21:20:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-29T16:20:00-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '520f1b86-ad50-4b78-8bde-aece08cb7b17'	System	29 Mar 2021 21:20:11
User entered 'No (N)'	System	29 Mar 2021 21:20:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-29T16:20:06-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '520f1b86-ad50-4b78-8bde-aece08cb7b17'	System	29 Mar 2021 21:20:11
User entered '29 Mar 2021 16:20:06'	System	29 Mar 2021 21:20:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-04T09:37:41-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '71562868-0919-416c-9f62-1a9451763c2d'	System	04 Apr 2021 14:37:51
User entered 'No (N)'	System	04 Apr 2021 14:37:51

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-04T09:37:45-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '71562868-0919-416c-9f62-1a9451763c2d'	System	04 Apr 2021 14:37:51
User entered 'No (N)'	System	04 Apr 2021 14:37:51

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-04T09:37:49-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '71562868-0919-416c-9f62-1a9451763c2d'	System	04 Apr 2021 14:37:51
User entered '04 Apr 2021 09:37:49'	System	04 Apr 2021 14:37:51

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-12T13:29:09-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '949dc8b3-40b3-4769-806d-24c2f0db5d2c' User entered 'No (N)'	System	12 Apr 2021 18:29:18
	System	12 Apr 2021 18:29:18

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-12T13:29:11-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '949dc8b3-40b3-4769-806d-24c2f0db5d2c'	System	12 Apr 2021 18:29:18
User entered 'No (N)'	System	12 Apr 2021 18:29:18

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-12T13:29:15-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '949dc8b3-40b3-4769-806d-24c2f0db5d2c'	System	12 Apr 2021 18:29:18
User entered '12 Apr 2021 13:29:15'	System	12 Apr 2021 18:29:18

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-18T21:58:19-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd2a7eab4-c52f-4b1c-b443-b4f9c23b9336'	System	19 Apr 2021 02:58:27
User entered 'No (N)'	System	19 Apr 2021 02:58:27

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-18T21:58:21-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd2a7eab4-c52f-4b1c-b443-b4f9c23b9336'	System	19 Apr 2021 02:58:27
User entered 'No (N)'	System	19 Apr 2021 02:58:27

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-18T21:58:25-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: 'd2a7eab4-c52f-4b1c-b443-b4f9c23b9336'	System	19 Apr 2021 02:58:27
User entered '18 Apr 2021 21:58:25'	System	19 Apr 2021 02:58:27

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-26T09:29:11-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9fb4297a-7eee-4993-8d84-e45ce20b66e1' User entered 'No (N)'	System	26 Apr 2021 14:29:30
	System	26 Apr 2021 14:29:30

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-26T09:29:14-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9fb4297a-7eee-4993-8d84-e45ce20b66e1' User entered 'No (N)'	System	26 Apr 2021 14:29:30

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-04-26T09:29:27-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '9fb4297a-7eee-4993-8d84-e45ce20b66e1' User entered '26 Apr 2021 09:29:27'	System	26 Apr 2021 14:29:30
	System	26 Apr 2021 14:29:30

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-05-03T12:05:11-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5c3cc7f6-0229-42e4-8edf-6d2cda1cf2cb'	System	03 May 2021 17:10:09
User entered 'No (N)'	System	03 May 2021 17:10:09

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

Have you been exposed to someone with 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 (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-05-03T12:05:17-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5c3cc7f6-0229-42e4-8edf-6d2cda1cf2cb'	System	03 May 2021 17:10:09
User entered 'No (N)'	System	03 May 2021 17:10:09

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-05-03T12:05:21-05:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '5c3cc7f6-0229-42e4-8edf-6d2cda1cf2cb'	System	03 May 2021 17:10:09
User entered '03 May 2021 12:05:21'	System	03 May 2021 17:10:09

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 18:56:11

US3312325

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:56:11
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 18:56:11

US3312325

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:59:14

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 16:33:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-01T12:12:19-06:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4e2904b7-9760-4147-a223-735a1556a568'	System	01 Mar 2021 18:19:16
User entered 'Yes (Y)'	System	01 Mar 2021 18:19:16

US3312325

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:59:14

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:33:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-01T12:12:56-06:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4e2904b7-9760-4147-a223-735a1556a568'	System	01 Mar 2021 18:19:16
User entered 'No (N)'	System	01 Mar 2021 18:19:16

US3312325

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:59:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:33:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4102A8-A34D-41C4-BC65-05B5975A46E1)', Time: '2021-03-01T12:13:16-06:00', User OID: 'PatientReportedOutcome (US3312325)', ODM File OID: '4e2904b7-9760-4147-a223-735a1556a568'	System	01 Mar 2021 18:19:16
User entered '01 Mar 2021 18:13:16'	System	01 Mar 2021 18:19:16

US3312325

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:16:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 15:56:25

US3312325

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:16:45
User entered '19 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 15:56:25

US3312325

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:16:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Nov 2020 15:56:25

US3312325

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:16:45
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 15:56:25

US3312325

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:16:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 15:56:41

US3312325

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:31:59
User entered 'I'	System	20 Nov 2020 15:56:41

US3312325

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:55:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 15:24:53

US3312325

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:55:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
User entered '21 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 15:24:53

US3312325

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:55:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Dec 2020 15:24:53

US3312325

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:55:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 15:24:53

US3312325

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:56:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 15:24:40

US3312325

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User entered 'I'	System	28 Dec 2020 15:24:40

US3312325

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:17:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 21:32:55

US3312325

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:17:40
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 21:32:55

US3312325

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:17:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Jan 2021 21:32:55

US3312325

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:17:40
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 21:32:55

US3312325

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:17:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 21:32:42

US3312325

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User entered 'I'	System	22 Jan 2021 21:32:42

US3312325

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 18:39:45

US3312325

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:18:09
User entered '18 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 18:39:45

US3312325

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Feb 2021 18:39:45

US3312325

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:18:09
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 18:39:45

US3312325

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:18:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 18:39:49

US3312325

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:10:54
User entered 'I'	System	19 Feb 2021 18:39:49

US3312325

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:05

US3312325

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:05

US3312325

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[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 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:39
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:05

US3312325

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
User entered 'VISIT4'	System	15 Mar 2021 17:41:05

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:49
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:49
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:49
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
User entered empty.	System	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:49
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:49
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:49
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:49
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
User entered empty.	System	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:49
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
User entered empty.	System	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:49
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
User entered empty.	System	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:49
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
User entered empty.	System	30 Mar 2021 17:06:16

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40

US3312325

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40

US3312325

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:07

US3312325

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:04:58
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:07

US3312325

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:19

US3312325

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:19

US3312325

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '10:13'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:19

US3312325

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
User entered '15 Mar 2021 10:13'	System	15 Mar 2021 17:41:19

US3312325

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:23
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:40:51

US3312325

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:47:40
User entered 'I'	System	15 Mar 2021 17:40:51

US3312325

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

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:34:11
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:31:06

US3312325

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

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:34:11
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:31:06

US3312325

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

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:34:11
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:31:06

US3312325

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

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 22:31:06

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:36:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:31:27

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:06:53

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:36:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:31:27

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
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 14:06:53

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:36:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:31:27

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:36:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:31:27

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:36:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 08:33:57
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	12 Jan 2021 22:31:27

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:36:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 08:33:57
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	12 Jan 2021 22:31:27

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:36:47
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:31:27

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered '1'	System	12 Jan 2021 22:31:27

US3312325

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

Form: Unblinding

Generated On: 09 Jun 2021 16:59:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'I'	System	12 Jan 2021 22:31:27

US3312325

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered empty.	System	12 Jan 2021 22:32:50
DataPoint set to visible.	System	12 Jan 2021 22:31:27

US3312325

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered empty.	System	12 Jan 2021 22:32:50
DataPoint set to visible.	System	12 Jan 2021 22:31:27

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '10:20'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered '11 Jan 2021 10:20'	System	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '67'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'bpm'	System	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '14'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'breaths/min'	System	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '110'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'mmHg'	System	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '64'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'mmHg'	System	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered empty.	System	12 Jan 2021 22:32:50
DataPoint set to visible.	System	12 Jan 2021 22:31:27

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '12:06'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered '11 Jan 2021 12:06'	System	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '67'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'bpm'	System	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '14'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'breaths/min'	System	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '133'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'mmHg'	System	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:40:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '79'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:50

US3312325

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'mmHg'	System	12 Jan 2021 22:32:50

US3312325

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:47:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:58

US3312325

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:47:54
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:32:58

US3312325

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

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:48:28
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:33:17

US3312325

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

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:48:28
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:33:17

US3312325

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

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:48:28
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:33:17

US3312325

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

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'mRNA-1273'	System	12 Jan 2021 22:33:17
DataPoint set to visible.	System	12 Jan 2021 22:31:27

US3312325

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

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:48:28
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:33:17

US3312325

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

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:48:28
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '11:35'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:33:17

US3312325

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

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered '11 Jan 2021 11:35'	System	12 Jan 2021 22:33:17

US3312325

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

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:48:28
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:33:17

US3312325

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

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:48:28
User entered 'ONCE'	System	12 Jan 2021 22:33:17

US3312325

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

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 22:33:17

US3312325

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:49:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:30:48

US3312325

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:49:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:30:48

US3312325

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:49:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '09:49'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:30:48

US3312325

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered '11 Jan 2021 09:49'	System	12 Jan 2021 22:30:48

US3312325

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:49:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:30:12

US3312325

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:59:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:49:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:30:12

US3312325

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:59:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:49:17
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '09:48' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:30:28
User entered '09:49'	(b) (4), (b) (6)	12 Jan 2021 22:30:12

US3312325

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:59:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered '11 Jan 2021 09:48'	System	12 Jan 2021 22:30:28
User entered '11 Jan 2021 09:49'	System	12 Jan 2021 22:30:12

US3312325

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

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:49:25
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:33:26

US3312325

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

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'I'	System	12 Jan 2021 22:33:26

US3312325

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:50:06
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:33:47

US3312325

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:50:06
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:33:47

US3312325

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:50:06
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:33:47

US3312325

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:50:06
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:33:47

US3312325

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:50:14
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:33:51

US3312325

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'I'	System	22 Jan 2021 21:33:51

US3312325

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'I'	System	22 Jan 2021 21:33:51
DataPoint set to visible.	System	22 Jan 2021 21:33:51

US3312325

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:51:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:27:50

US3312325

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:51:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:27:50

US3312325

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:51:18
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:27:50

US3312325

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'OLD29'	System	19 Feb 2021 18:27:50

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '09:26'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered '08 Feb 2021 09:26'	System	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '66'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'bpm'	System	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'breaths/min'	System	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '123'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'mmHg'	System	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '73'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'mmHg'	System	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 18:38:05
User entered '08 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 18:38:05
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 18:37:51
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 18:38:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Feb 2021 18:38:05
User entered '10:45' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 18:38:05
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 18:37:51
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered '08 Feb 2021 10:45'	System	19 Feb 2021 18:38:05
User entered empty.	System	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '60'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'bpm'	System	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'breaths/min'	System	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '115'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'mmHg'	System	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:08
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '64'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'mmHg'	System	19 Feb 2021 18:37:51

US3312325

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:21
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:38:16

US3312325

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:52:21
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:38:16

US3312325

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:54:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:38:37

US3312325

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:54:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:38:37

US3312325

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:54:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:38:37

US3312325

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'mRNA-1273'	System	19 Feb 2021 18:38:37
DataPoint set to visible.	System	22 Jan 2021 21:33:51

US3312325

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:54:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:38:37

US3312325

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:54:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '10:15'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:38:37

US3312325

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered '08 Feb 2021 10:15'	System	19 Feb 2021 18:38:37

US3312325

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:54:55
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:38:37

US3312325

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:54:55
User entered 'ONCE'	System	19 Feb 2021 18:38:37

US3312325

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 18:38:37

US3312325

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:55:04
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:38:40

US3312325

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'I'	System	19 Feb 2021 18:38:40

US3312325

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:39:12

US3312325

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:39:12

US3312325

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:39:12

US3312325

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:20
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:39:12

US3312325

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:39:14

US3312325

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'I'	System	19 Feb 2021 18:39:14

US3312325

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:43

US3312325

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:43

US3312325

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:56
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:43

US3312325

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered 'OLD57'	System	15 Mar 2021 17:41:43

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered empty.	System	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered empty.	System	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered empty.	System	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered empty.	System	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:16
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered empty.	System	15 Mar 2021 17:41:48

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18

US3312325

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18

US3312325

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:28
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:52

US3312325

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:28
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:41:52

US3312325

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:42:02

US3312325

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:42:02

US3312325

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:06:34
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered '10:13'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:42:02

US3312325

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:08:18
User entered '15 Mar 2021 10:13'	System	15 Mar 2021 17:42:02

US3312325

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:59:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:58
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:16:12

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Nov 2020 18:18:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 18:18:35
Data point term sent to Coder	System	09 Nov 2020 18:18:02
User entered 'URINARY TRACT INFECTION'	(b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '31 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
User entered empty.	System	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
User entered empty.	System	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'l'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
User entered '0'	System	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39
User entered '1'	System	09 Nov 2020 18:17:26

US3312325

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:28:39

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered	(b) (4)	17 Dec 2020 20:22:22
'USA-US300-2020-mRNA-1273-P301000020'	System	17 Dec 2020 20:22:22
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:22
User entered 'New' reason for change: Data Entry	(b) (4), (b) (6)	17 Dec 2020 20:22:22
Error		
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:21:43
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 20:21:34

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Pelvic prolapse conditions, PT: Pelvic prolapse, LLT: Pelvic prolapse - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 13:44:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 13:44:39
Data point term sent to Coder	System	08 Jan 2021 01:39:05
Coding entries removed.	(b) (4), (b) (6)	08 Jan 2021 01:38:56
User entered 'worsening of pelvic organ prolapse' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 01:38:56
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Pelvic prolapse conditions, PT: Rectocele, LLT: Rectocele - version MedDRA\23.0.	Coder Import (b) (4)	17 Dec 2020 11:18:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Dec 2020 11:18:44
Data point term sent to Coder	System	16 Dec 2020 19:57:19
User entered 'worsening of rectocele'	(b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 01:38:56
User entered '11 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 01:38:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 01:38:56
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[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)	19 Jan 2021 16:32:05
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:41:58
User entered empty.	System	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	16 Dec 2020 19:57:32
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Dec 2020 19:57:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	16 Dec 2020 19:57:32
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		16 Dec 2020 19:57:32
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 19:57:32
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	16 Dec 2020 19:57:15
User entered '0'	(b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User closed query 'Per CDM-Concomitant Medication is ticked, however, corresponding conmed with same matching indication 'WORSENING OF RECTOCELE' is not recorded on conmed page.Kindly consider to verify and update the indication recorded else clarify.' (Site from DM). Query 'Per CDM-Concomitant Medication is ticked, however, corresponding conmed with same matching indication 'WORSENING OF RECTOCELE' is not recorded on conmed page.Kindly consider to verify and update the indication recorded else clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:19:13
User opened query 'Per CDM-Concomitant Medication is ticked, however, corresponding conmed with same matching indication 'WORSENING OF RECTOCELE' is not recorded on conmed page.Kindly consider to verify and update the indication recorded else clarify.' (Site from DM). User entered 'I'	(b) (4), (b) (6)	08 Jan 2021 01:37:45
	(b) (4), (b) (6)	23 Dec 2020 09:02:10
	(b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 11:52:46
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 16:17:17
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 01:42:24
User entered 'I'	(b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 13:26:27
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 01:39:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	08 Jan 2021 01:38:56
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:47:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:57:35
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:56:09
User closed query 'Per DM CLR: Narrative indicates that the subject underwent SACROSPINOUS FIXATION, PERINORRHAPHY AND CYSTOSCOPY. However, there is no recorded Concomitant Procedures that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 07:43:16
User closed query 'Per DM CLR: Narrative indicates that there was also a CYSTOCELE noted. However, there is no MH or AE record that match the information. Please update or record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:12:01
Query 'Per DM CLR: Narrative indicates that the subject underwent SACROSPINOUS FIXATION, PERINORRHAPHY AND CYSTOSCOPY. However, there is no recorded Concomitant Procedures that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' answered with 'Updated Con procedure page' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:17:43
Query 'Per DM CLR: Narrative indicates that there was also a CYSTOCELE noted. However, there is no MH or AE record that match the information. Please update or record the corresponding MH or AE as appropriate. Otherwise, clarify.' answered with 'updated MH' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:17:30
User opened query 'Per DM CLR: Narrative indicates that the subject underwent SACROSPINOUS FIXATION, PERINORRHAPHY AND CYSTOSCOPY. However, there is no recorded Concomitant Procedures that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 05:22:54

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that there was also a CYSTOCELE noted. However, there is no MH or AE record that match the information. Please update or record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 05:22:42
User entered '71 YEAR OLD FEMALE WITH DISTANT HISTORY OF HYSTEROSALPINGECTOMY AND A 5 YEAR HISTORY OF SLOWLY PROGRESSIVE RECTOCELE WAS ADVISED BY PCP AT RECENT ANNUAL PHYSICAL TO REPAIR SURGICALLY. SUBJECT DID NOT PERCEIVE SIGNIFICANT WORSENING AND CONSIDERED THE OPTION FOR MONTHS PRIOR TO RECENTLY UNDERGOING THE PROCEDURE. SHE WAS HOSPITALIZED FOR MORE THAN 24 HOURS AS PART OF THE SURGERY, WHICH WENT WITHOUT COMPLICATIONS. SHE WAS ADMITTED 11DEC2020 THROUGH 12DEC2020 AND WAS DISCHARGED ON PAIN MEDICATIONS. HER COVID TEST WAS NEGATIVE. SHE SOUNDS WELL ON THE PHONE CALL TODAY. POST OP FOLLOW-UP WITH HER GYNECOLOGIST IS 23DEC2020. WILL OBTAIN MED RECORDS.	(b) (4), (b) (6)	08 Jan 2021 01:38:56
Update:Medical records received, confirming that subject underwent elective surgical procedure to repair rectocele but also cystocele. Procedure was anterior and posterior repair, sacrospinous fixation, perinorrhaphy, and cystoscopy. Patient tolerated it well and had no complications. Will close SAE, not related to IP, of moderate severity.' reason for change: Data Entry Error		

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Narrative](#)

Audit	User	Time (GMT)
User entered '71 year old female with distant history of hysterosalpingectomy and a 5 year history of slowly progressive rectocele was advised by PCP at recent annual physical to repair surgically. Subject did not perceive significant worsening and considered the option for months prior to recently undergoing the procedure. She was hospitalized for more than 24 hours as part of the surgery, which went without complications. She was admitted 11Dec2020 through 12Dec2020 and was discharged on pain medications. Her Covid test was negative. She sounds well on the phone call today. Post op follow-up with her Gynecologist is 23Dec2020. Will obtain med records.'	(b) (4), (b) (6)	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	16 Dec 2020 19:57:15

US3312325

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
User entered '0'	System	16 Dec 2020 19:57:15

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:56
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:34:59
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'CONCOMITANT MEDICATIONS ADDED' (Site from DM).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:56:42
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:04:58
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:37:40
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:26:27

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:12:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:12:52
Data point term sent to Coder	System	04 Sep 2020 18:27:44
User entered 'SYMBICORT (BUDESONIDE/FORMOTEROL)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'ASTHMA'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User closed query 'Per DM CLR: Please review the dose and Dose Unit recorded as this is not the standard dose for this medication (80/4.5 ug). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 08:19:27
Query 'Per DM CLR: Please review the dose and Dose Unit recorded as this is not the standard dose for this medication (80/4.5 ug). Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 01:40:13
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 01:40:06
User entered '80/4.5' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 01:40:06
User opened query 'Per DM CLR: Please review the dose and Dose Unit recorded as this is not the standard dose for this medication (80/4.5 ug). Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 10:48:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:01:29
User closed query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:16:35
Query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly.' answered with 'Updated dose. Thanks.' (Site from DM).	Heather Barker (b) (4) (b) (4)	23 Oct 2020 16:01:33
DataPoint Un-verified.	Heather Barker (b) (4) (b) (4)	23 Oct 2020 16:01:23
User entered '80/45' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	23 Oct 2020 16:01:23

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered, as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 13:24:43
	(b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '1'	Karol Moore (b) (4)	04 Sep 2020 18:27:26
	(b) (4)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4)	29 Oct 2020 21:01:29
DataPoint Un-verified.	(b) (4), (b) (6)	
	Heather Barker (b) (4)	23 Oct 2020 16:01:23
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Heather Barker (b) (4)	23 Oct 2020 16:01:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'puff (PUFF)'	Karol Moore (b) (4)	04 Sep 2020 18:27:26
	(b) (4)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4)	04 Sep 2020 18:27:26
	(b) (4)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'UN Jul 2018'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 18:27:26

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 20:41:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:58:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:58:47
Data point term sent to Coder	System	04 Sep 2020 18:28:45
User entered 'ALBUTEROL (90MCG)'	Karol Moore (b) (4)	04 Sep 2020 18:27:55
	(b) (4)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'ASTHMA'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '2'	Karol Moore (b) (4)	04 Sep 2020 18:27:55
	(b) (4)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'puff (PUFF)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'UN UNK 1970'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:27:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:29:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:29:41
Data point term sent to Coder	System	04 Sep 2020 18:28:45
User entered 'VITAMIN D'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'GENERAL HEALTH MAINTENANCE'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '2000'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'IU (IU)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'UN UNK 2018'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 18:28:32

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: COLLAGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:24:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:24:47
Data point term sent to Coder	System	04 Sep 2020 18:29:48
User entered 'COLLAGEN (POWDER)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'GENERAL HEALTH MAINTENANCE'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'I'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'TEASPOON'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'UN Mar 2020'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 18:29:13

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 14:58:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 14:58:35
Data point term sent to Coder	System	17 Sep 2020 14:58:05
Coding entries removed.	Karol Moore (b) (4)	17 Sep 2020 14:57:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 18:31:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 18:31:47
Data point term sent to Coder	System	04 Sep 2020 18:30:49
User entered 'ACETAMINOPHEN'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 18:40:50
User closed query 'Please verify spelling of condition and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 18:40:47
Query 'Please verify spelling of condition and update if needed. ' answered with 'UPDATED' (Site from CRA).	Karol Moore (b) (4)	17 Sep 2020 14:57:37
	(b) (4)	
User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error	Karol Moore (b) (4)	17 Sep 2020 14:57:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 20:41:08
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:41:02
	(b) (4), (b) (6)	
User opened query 'Please verify spelling of condition and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 20:38:53
User entered 'OSTEOARTHRITIDS500'	Karol Moore (b) (4)	04 Sep 2020 18:30:02
	(b) (4)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 18:40:54
User closed query 'Per source dose is 500 mg. Please verify dose and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 18:40:52
Query 'Per source dose is 500 mg. Please verify dose and update if needed. ' answered with 'UPDATED' (Site from CRA).	Karol Moore (b) (4)	17 Sep 2020 14:57:43
	(b) (4)	
User entered '500' reason for change: Data Entry Error	Karol Moore (b) (4)	17 Sep 2020 14:57:31
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 20:41:10
DataPoint Verified.	(b) (4), (b) (6)	15 Sep 2020 20:41:02
User opened query 'Per source dose is 500 mg. Please verify dose and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 20:39:48
User entered '800'	Karol Moore (b) (4)	04 Sep 2020 18:30:02
	(b) (4)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'UN UNK 2015'	Karol Moore (b) (4)	04 Sep 2020 18:30:02
	(b) (4)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '0'	Karol Moore (b) (4)	04 Sep 2020 18:30:02
	(b) (4)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:30:02

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:21:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:21:47
Data point term sent to Coder	System	04 Sep 2020 18:30:53
User entered 'CETRIZINE'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'ALLERGY TO RHINITIS'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '10'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'UN Mar 2020'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:30:40

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DOXYLAMINE SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:32:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:32:42
Data point term sent to Coder	System	04 Sep 2020 18:31:56
User entered 'DOXYLAMINE SUCCINATE'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'INSOMNIA'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '50'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	04 Sep 2020 18:31:50
User entered 'other (OTHER)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:50
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	04 Sep 2020 18:31:43
User entered 'once (ONCE)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'NIGHTLY'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'UN UNK 2010'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered '0'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered empty.	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:41:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 18:31:43

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: FLUZONE [INFLUENZA VACCINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 00:31:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 00:31:54
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:01:29
Data point term sent to Coder	System	29 Oct 2020 15:33:13
User entered 'FLUZONE'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered 'SEASONAL INFLUENZA PROPHYLAXIS'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered 'l'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered 'Other (OTHER)'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered 'INJECTION'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered '25 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered '25 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:01:29
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User entered empty.	System	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User entered empty.	System	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:20
User entered empty.	System	29 Oct 2020 15:32:16

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 19:29:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	10 Feb 2021 19:29:51
Data point term sent to Coder	System	10 Feb 2021 19:29:47
Coding entries removed.	(b) (4), (b) (6)	10 Feb 2021 19:28:49
User entered 'trimethoprim/sulfamethoxazole' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 19:28:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 18:16:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Nov 2020 18:16:34
Data point term sent to Coder	System	09 Nov 2020 18:15:59
User entered 'Bactrim'	(b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'URINARY TRACT INFECTION'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 800/160).' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 10:06:59
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 800/160).' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 19:28:57
User entered '800/160' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 19:28:49
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 800/160).' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 10:49:27
User entered '1600'	(b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '31 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
User entered '2'	System	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
User entered '1'	System	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:23
User entered '804 (804)'	System	09 Nov 2020 18:15:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: TRIMETHOPRIM SULFAMETHOXAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 13:57:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 13:57:57
Data point term sent to Coder	System	10 Feb 2021 19:29:45
Coding entries removed.	(b) (4), (b) (6)	10 Feb 2021 19:29:10
User entered 'trimethoprim/sulfamethoxazole' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 19:29:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Jan 2021 14:25:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Jan 2021 14:25:40
Data point term sent to Coder	System	08 Jan 2021 02:30:10
User entered 'bactrimDS'	(b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Post surgery infection prophylaxis'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 10:07:17
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 19:29:22
User entered '800/160' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 19:29:10
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components using slash (e.g. 5/325).' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:28:54
User entered '1600'	(b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
User entered '2'	System	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
User entered '1'	System	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:27
User entered '804 (804)'	System	08 Jan 2021 02:29:55

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Jan 2021 14:43:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:43:40
Data point term sent to Coder	System	08 Jan 2021 02:31:11
User entered 'celecoxib'	(b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'worsening of pelvic organ prolapsa'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '100'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
User entered empty.	System	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
User entered empty.	System	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:30
User entered empty.	System	08 Jan 2021 02:30:50

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 14:30:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 14:30:42
Data point term sent to Coder	System	07 Apr 2021 13:46:01
User entered 'ESTRADIOL CREAM' reason for change: Data Entry Error	Karol Moore (b) (4)	07 Apr 2021 13:45:06
Data point term sent to Coder	System	07 Apr 2021 13:43:59
Coding entries removed.	Karol Moore (b) (4)	07 Apr 2021 13:43:35
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 12:26:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 12:26:56
Data point term sent to Coder	System	10 Feb 2021 19:30:48
User entered 'estradiol'	(b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:34:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' answered with 'UPDATED. SUBJECT PRESCRIBED FOR HORMONE REPLACEMENT THERAPY DUE TO RECTOCELE REPAIR' (Site from DM).	Karol Moore (b) (4)	07 Apr 2021 13:46:13
User entered 'RECTOCELE REPAIR' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:43:35
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 10:44:36
User entered 'hormone replacement therapy'	(b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '2' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:47:08
User entered '1'	Karol Moore (b) (4)	10 Feb 2021 19:30:39
	(b) (4)	
	(b) (4), (b) (6)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:34:50
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'UPDATED PER SOURCE' (Site from DM).	Karol Moore (b) (4)	07 Apr 2021 13:47:54
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 10:44:45
User entered 'g (g)'	(b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:34:52
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'CORRECT AS ENTERED. ESTRADIOL CREAM IS ADMINISTERED VAGINALLY' (Site from DM).	Karol Moore (b) (4)	07 Apr 2021 13:48:27
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 10:44:51
User entered 'Vaginal (VAGINAL)'	(b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:45:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '29 Jan 2021' reason for change: Data Entry Error	(b) (4)	07 Apr 2021 13:45:27
User entered empty.	Karol Moore (b) (4)	10 Feb 2021 19:30:39
	(b) (4), (b) (6)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
User entered '1'	System	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
User entered '1'	System	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:26:33
User entered '804 (804)'	System	10 Feb 2021 19:30:39

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A HAEMAGGLUTININ COMPLEX, PRODUCTSYNONYM: DYSPORT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 13:49:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 13:49:38
Data point term sent to Coder Coding entries removed.	System Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:49:05 07 Apr 2021 13:48:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A HAEMAGGLUTININ COMPLEX, PRODUCTSYNONYM: DYSPORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4) (b) (4)	11 Mar 2021 15:57:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 15:57:51
Data point term sent to Coder User entered 'Dysport'	System (b) (4), (b) (6)	11 Mar 2021 15:57:17 11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 23:09:12
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' ' answered with 'UPDATED' (Site from DM).	(b) (4)	
User entered 'COSMETIC PROPHYLAXIS' reason for change: Data Entry Error	Karol Moore (b) (4)	07 Apr 2021 13:49:09
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.)' ' (Site from DM).	(b) (4)	
User entered 'cosmetic'	Karol Moore (b) (4)	07 Apr 2021 13:48:52
	(b) (4)	
	(b) (4), (b) (6)	21 Mar 2021 01:00:01
	(b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'injection'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'un Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'un Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
User entered empty.	System	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
User entered empty.	System	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:01
User entered empty.	System	11 Mar 2021 15:56:53

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 14:30:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 14:30:42
Data point term sent to Coder	System	07 Apr 2021 13:56:14
User entered 'ESTRADIOL CREAM'	Karol Moore (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'RECTOCELE REPAIR'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '2'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'g (g)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'ONCE EVERY 3 DAYS'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Vaginal (VAGINAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4)	07 Apr 2021 13:55:21
	Karol Moore (b) (4)	
	(b) (4)	

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '30 Jan 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:32:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:52
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 13:55:21

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:59:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:58
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:27:38
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:00:27

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:59:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:00:46

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:59:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered 'RECTOCELE/cystocele REPAIR'	(b) (4)	08 Jan 2021 01:39:44
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'rectocele repair'	(b) (4), (b) (6)	16 Dec 2020 20:00:46

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Jan 2021 16:17:03
User entered 'Medical History (MH)'	(b) (4), (b) (6)	16 Dec 2020 20:00:46

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:59:14

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:00:46

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:59:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:24:35

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:59:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered 'sacrospinous fixation'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:24:35

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:24:35

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:59:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:24:35

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:59:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:32
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:25:41

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:59:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:32
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered 'perineorrhaphy'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:25:41

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:32
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:25:41

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:59:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:32
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:25:41

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:59:14

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:36
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:25:59

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:59:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:36
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered 'cystoscopy'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:25:59

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:59:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:36
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:25:59

US3312325

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:59:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:52:36
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:50:05
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:22:18
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:25:59

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'USA-US300-2020-MRNA-1273-P301000020'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Yes (Y)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Yes (Y)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Carlos'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Fierro'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered '16300 College Blvd'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Shawnee'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'KS'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered '66219'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 13:26:35
User entered 'US'	System	17 Dec 2020 20:23:01

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Jan 2021 13:26:43
User entered '1'	System	17 Dec 2020 20:23:01

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'USA-US300-2020-MRNA-1273-P301000020'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Yes (Y)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Yes (Y)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Carlos'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Fierro'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered '16300 College Blvd'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Shawnee'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'KS'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered '66219'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 13:26:35
User entered 'US'	System	17 Dec 2020 20:23:01

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Jan 2021 13:26:43
User entered '1'	System	17 Dec 2020 20:23:01

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:59:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
User entered '17/Dec/2020 15:22'	System	17 Dec 2020 20:23:01

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:59:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 13:26:35
User entered 'I'	(b) (4), (b) (6)	17 Dec 2020 20:23:01

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'USA-US300-2020-MRNA-1273-P301000020'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Yes (Y)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Yes (Y)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'No (N)'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Carlos'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Fierro'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered '16300 College Blvd'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'Shawnee'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered 'KS'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:22:43
User entered '66219'	System	17 Dec 2020 20:22:22

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 13:26:35
User entered 'US'	System	17 Dec 2020 20:23:01

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Jan 2021 13:26:43
User entered '1'	System	17 Dec 2020 20:23:01

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:59:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
User entered '08/Jan/2021 08:26'	System	08 Jan 2021 13:26:43

US3312325

Folder: SAE USA-US300-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:59:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 01:23:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 22:03:02
User entered 'I'	(b) (4), (b) (6)	08 Jan 2021 13:26:43