

US3322314 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:08:30

All time stamps listed in this document are displayed in GMT

US3322314

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 03:54:27

Generated On: 09 Jun 2021 17:08:30

Participant ID

US3322314

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

US3322314

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Date of Informed Consent (*dd MMM yyyy*) 11 SEP 2020

Month and Year of Informed Consent (derived) SEP 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Feb 2021 03:54:28

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Condition	ROSACEA
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Condition	DEXTROCARDIA
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Condition	AORTIC STENOSIS
Start date (dd MMM yyyy)	(b) (6) 1974
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 FEB 1985
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1974
Start Year (derived)	1974
Stop Month and Year (derived)	FEB 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Condition	AORTIC STENOSIS REPAIR SURGERY
Start date (dd MMM yyyy)	UN FEB 1985
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 FEB 1985
Stop date completely unknown	False
Start Month and Year (derived)	FEB 1985
Start Year (derived)	1985
Stop Month and Year (derived)	FEB 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Condition	CORONARY ATHEROSCLEROSIS
Start date (dd MMM yyyy)	23 AUG 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	23 AUG 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Condition	PALPITATION
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:50 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 08:50
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	190.2 lb
BMI (<i>xxx.x</i>)	29.85182 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:54:28

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 03:54:28

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

SUBJECT IS A SCHOOL
TEACHER WHO IS WORKING
FROM HOME.
FACE TO FACE TEACHING WILL
BE STARTING IN MIDDLE OF
OCT.

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 03:54:28

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Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
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)	True
Other	True
Specify	HIS PARTNER IS A MEDICAL TECHNOLOGIST WHO IS WORKING AT HOSPITAL 5 DAYS A WEEK. THE SUBJECT GOES TO THE GYM 3 TIMES A WEEK, GROCERIES LIKE 2 TIMES A WEEK, AND DINNING OUTSIDE 2 TIMES A WEEK.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

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

What was the participant's randomization number? 146219

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	08:57 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 08:57
Temperature (xxx.x)	97.0 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	11:23 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:23
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 10:50

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

10:17 (24 HR)

Collection date and time (derived)

11 SEP 2020 10:17

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:07	11 SEP 2020 10:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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

97.3 °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

11 SEP 2020 11:22

PC Open Date & Time

11 SEP 2020 11:10

PC Close Date & Time

11 SEP 2020 13:40

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp	11 SEP 2020 21:22
PC Open Date & Time	11 SEP 2020 14:35
PC Close Date & Time	12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 SEP 2020 19:06

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 18:17

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 22:52

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 16:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

16 SEP 2020 20:45

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 16:58

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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

11 SEP 2020 11:24

PC Open Date & Time

11 SEP 2020 11:10

PC Close Date & Time

11 SEP 2020 13:40

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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

11 SEP 2020 21:22

PC Open Date & Time

11 SEP 2020 14:35

PC Close Date & Time

12 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

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

2

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

12 SEP 2020 19:07

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 18:17

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

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

14 SEP 2020 22:52

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 16:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 20:46

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 16:58

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 11:25
PC Open Date & Time	11 SEP 2020 11:10
PC Close Date & Time	11 SEP 2020 13:40

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 14:36
PC Open Date & Time	11 SEP 2020 14:35
PC Close Date & Time	12 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:07
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

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

52 of 2276

EAB) (1725)

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:18
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

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)

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US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 22:53
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

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

56 of 2276

EAB) (1725)

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 16:03
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

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 ☒

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:46
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

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 ☒

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 16:58
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3322314

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322314

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322314

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322314

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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	VISIT2

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

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)	9 OCT 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 10:30
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 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)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

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)	9 OCT 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 11:55
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3322314

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

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) 09 OCT 2020

What was the treatment time? (00:00-23:59) 11:25 (24 HR)

Treatment Date and Time (derived) 09 OCT 2020 11:25

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

What was the frequency of the study treatment dosing? ONCE

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

US3322314

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 OCT 2020
Collection time (00:00-23:59)	11:10 (24 HR)
Collection date and time (derived)	09 OCT 2020 11:10

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Collection date (dd MMM yyyy)			09 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:05	09 OCT 2020 11:05
Nasopharyngeal Swab 2	No		

US3322314

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

09 OCT 2020 11:57

PC Open Date & Time

09 OCT 2020 11:45

PC Close Date & Time

09 OCT 2020 14:15

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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	09 OCT 2020 16:20
PC Open Date & Time	09 OCT 2020 15:10
PC Close Date & Time	10 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 15:11

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 15:13

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 04:51

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 20:28

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 17:44

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

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.

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 19:39

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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

09 OCT 2020 11:57

PC Open Date & Time

09 OCT 2020 11:45

PC Close Date & Time

09 OCT 2020 14:15

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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

09 OCT 2020 16:21

PC Open Date & Time

09 OCT 2020 15:10

PC Close Date & Time

10 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

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

10 OCT 2020 15:11

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

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

11 OCT 2020 15:14

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

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

13 OCT 2020 04:51

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

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

13 OCT 2020 20:28

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

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

14 OCT 2020 17:44

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

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

15 OCT 2020 19:39

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 11:58
PC Open Date & Time	09 OCT 2020 11:45
PC Close Date & Time	09 OCT 2020 14:15

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 16:21
PC Open Date & Time	09 OCT 2020 15:10
PC Close Date & Time	10 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

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 ☒

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 04:52
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 20:28
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

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 ☒

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 17:44
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

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

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EAB) (1725)

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 19:39
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3322314

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322314

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322314

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322314

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 NOV 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

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:32 (24 HR)
Vital Signs Date and Time (derived)	3 NOV 2020 09:32
Temperature (<i>xxx.x</i>)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322314

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 NOV 2020

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

US3322314

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 NOV 2020
Collection time (00:00-23:59)	09:31 (24 HR)
Collection date and time (derived)	3 NOV 2020 09:31

US3322314

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 14:28:41
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 03:46:39

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 75
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 NOV 2020 07:35:16
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 07:42:38
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 DEC 2020 19:17:47
Patient Cloud Open Date & Time	06 DEC 2020 00:01
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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 DEC 2020 05:26:40
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

20 DEC 2020 07:40:15

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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	27 DEC 2020 07:13:42
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

03 JAN 2021 07:57:28

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 05:19:41
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

17 JAN 2021 07:57:33

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

24 JAN 2021 09:47:04

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

01 FEB 2021 05:07:01

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

08 FEB 2021 05:23:19

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 FEB 2021 07:14:00
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 08:15:50

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

01 MAR 2021 05:21:44

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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	07 MAR 2021 07:19:51
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

15 MAR 2021 06:21:15

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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	23 MAR 2021 12:00:49
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 08:04:25

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

04 APR 2021 08:07:27

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 <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	11 APR 2021 08:11:38
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

18 APR 2021 08:12:10

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

25 APR 2021 09:19:50

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	02 MAY 2021 05:26:33
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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°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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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°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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 <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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

Patient Cloud Open Date & Time	26 SEP 2021 00:01
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Patient Cloud Close Date & Time	30 SEP 2021 23:59
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US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

Patient Cloud Open Date & Time	03 OCT 2021 00:01
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Patient Cloud Close Date & Time	07 OCT 2021 23:59
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US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐ Yes ☐

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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="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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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°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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 <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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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="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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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="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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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°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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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"/>

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3322314

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:08:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 16:30:29

US3322314

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322314

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322314

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3322314

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 22:07:38

Generated On: 09 Jun 2021 17:08:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322314

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:07:38

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 APR 2021
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	02 APR 2021 10:15
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322314

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

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.

US3322314

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 APR 2021

Collection time (00:00-23:59)

10:33 (24 HR)

Collection date and time (derived)

02 APR 2021 10:33

US3322314

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322314

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Date of Contact	07 DEC 2020
Time of Contact	12:00
Date and Time of Contact (derived)	07 DEC 2020 12:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Date of Visit 07 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 07 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☐
Nasal Swab ☒
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	09 DEC 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 DEC 2020
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	07 DEC 2020 10:52
Height (xxx.x)	66 in
Weight (xxx.x)	192 lb
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322314

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 DEC 2020

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

US3322314

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 DEC 2020

US3322314

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

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

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

Visit date (dd MMM yyyy)	18 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3322314

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 22:07:38

Generated On: 09 Jun 2021 17:08:30

Date of updated informed consent (*dd MMM yyyy*) 18 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 18 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3322314

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

08:54 (24 HR)

Collection date and time (derived)

18 JAN 2021 08:54

US3322314

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Feb 2021 03:54:28

Generated On: 09 Jun 2021 17:08:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	08:49
Collection Date and Time (derived)	18 JAN 2021 08:49

US3322314

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Apr 2021 19:31:30

Generated On: 09 Jun 2021 17:08:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 16:33:16

Generated On: 09 Jun 2021 17:08:30

AEID

Adverse event

UPPER RESPIRATORY
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)

04 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

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 ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 16:33:16

Generated On: 09 Jun 2021 17:08:30

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	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)	

US3322314

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 16:33:16

Generated On: 09 Jun 2021 17:08:30

AEID	USA-US060-2021-MRNA-1273-P30 1000011
Adverse event	TRANSIENT ISCHEMIC ATTACK
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)	05 APR 2021
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)	06 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	05 APR 2021
Hospital Discharge Date (dd MMM yyyy)	06 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 16:33:16

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 16:33:16

Generated On: 09 Jun 2021 17:08:30

PATIENT CONTACTED STUDY SITE VIA TEXT MESSAGE TODAY TO REPORT HE IS BEING EVALUATED AT THE ER FOR SUSPECTED TIA (TRANSIENT ISCHEMIC ATTACK). PATIENT CONTACTED STUDY SITE VIA TEXT MESSAGE TODAY AND REPORTED EXPERIENCING VOMITING ON THE MORNING OF 05APR2021. UPON ARRIVAL TO WORK ON THE SAME DAY AT 7:11 AM, HE BEGAN EXPERIENCING SLURRED SPEECH AND DIFFICULTY WITH AMBULATION. PATIENT WAS SEEN BY HIS CARDIOLOGIST AT APPROXIMATELY 10:45 AM. HIS CARDIOLOGIST SUBSEQUENTLY SENT HIM TO THE ER FOR FURTHER EVALUATION AND MANAGEMENT. PATIENT ARRIVED TO THE ER AROUND 11:30 AM. AFTER EVALUATION BY ER PHYSICIAN, PATIENT WAS TOLD THAT HE MAY BE EXPERIENCING A TIA. AS OF 06APR2021 AT 10:33 AM, PATIENT IS STILL UNDER EVALUATION. WILL AWAIT FURTHER UPDATE FROM PATIENT REGARDING STATUS. WILL ALSO OBTAIN MEDICAL RECORDS WITH LABS AND RADIOLOGY FINDINGS.

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

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 03:54:27

Generated On: 09 Jun 2021 17:08:30

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	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)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Name of Medication METOPROLOL ER

Prophylaxis Yes ☐
No ☒

Indication PALPITATION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	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 APR 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN MAY 2017		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE HEALTHCARE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	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)		12 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)		12 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication IMMUNITY

Dose per administration 11

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

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

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Name of Medication CETIRIZINE (ZYRTEC)

Prophylaxis Yes ☐
No ☒

Indication ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	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)		07 DEC 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"/>

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Name of Medication (VITAMIN A), (VITAMIN C),
(VITAMIN E), (MAGNESIUM),
(ZINC), (SELENIUM),
(MANGANESE), (SODIUM),
(PROPRIETARY HERBAL
EXTRACT BLEND),
(PROPRIETARY AMINO ACID
BLEND) WAL-BORNE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration

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

If dose unit is Other, specify 600MCG/1000MG/13.5MG/40MG/8
MG/15MCG/3MG/150MG/350MG/5
0MG

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

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	other	<input type="checkbox"/>
If frequency is Other, specify		
Route of administration	Oral	<input checked="" type="checkbox"/>
	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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)	06 DEC 2020	
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"/>

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication ELEVATED BLOOD PRESSURE

Dose per administration 324

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	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)		05 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 05 APR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication TRANSIENT ISCHEMIC ATTACK

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	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)		09 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Name of Medication BYSTOLIC(NEBIVOLOL)

Prophylaxis Yes ☐
No ☒

Indication ELEVATED BLOOD PRESSURE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

	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)		09 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 APR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Apr 2021 19:31:30

Generated On: 09 Jun 2021 17:08:30

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 APR 2021	CT SCAN (NO ACUTE FINDING)	Diagnostic	
05 APR 2021	MRI (NO ACUTE FINDINGS)	Diagnostic	
09 APR 2021	EKG (UNREMARKABLE)	Adverse Event	

US3322314

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:08:30

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 ☐

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

SAEID	USA-US060-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

SAEID	USA-US060-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	07/APR/2021 08:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

SAEID	USA-US060-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/APR/2021 07:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

SAEID	USA-US060-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/APR/2021 12:33
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

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 16:33:17

Generated On: 09 Jun 2021 17:08:30

SAEID	USA-US060-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/APR/2021 10:21
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

US3322314 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322314

Form: Participant Creation

Generated On: 09 Jun 2021 17:08:30

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:20:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'US3322314'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:44:29

US3322314

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:17:22

US3322314

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:44:31

US3322314

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:17:22

US3322314

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'SCRN'	System	11 Sep 2020 17:17:22

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered (b) (6) 1974'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:44:32

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '46'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'YEARS'	System	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '46'	System	11 Sep 2020 15:59:52

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	1 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (u) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:20:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:18:43

US3322314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 Sep 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 15:59:52

US3322314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Sep 2020'	System	11 Sep 2020 15:59:52

US3322314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '2020'	System	11 Sep 2020 15:59:52

US3322314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Amendment 3 (3)'	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 15:59:52

US3322314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 15:59:52

US3322314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:30

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 15:59:52

US3322314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 15:59:52

US3322314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 15:59:52

US3322314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:44:31

US3322314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'I'	System	11 Sep 2020 15:59:57

US3322314

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 15:59:57

US3322314

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:08:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:19:20

US3322314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 17:22:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:22:48
Data point term sent to Coder	System	11 Sep 2020 17:20:45
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	11 Sep 2020 17:19:53

US3322314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'un UNK 1975'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:19:53

US3322314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:19:53

US3322314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:19:53

US3322314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:19:53

US3322314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (u) (4), (b) (6)	11 Sep 2020 17:19:53

US3322314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Jan 1975'	System	11 Sep 2020 17:19:53

US3322314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '1975'	System	11 Sep 2020 17:19:53

US3322314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:19:53

US3322314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:19:53

US3322314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 17:22:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:22:44
Data point term sent to Coder	System	11 Sep 2020 17:20:45
User entered 'Rosacea'	(b) (4), (b) (6)	11 Sep 2020 17:20:07

US3322314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:20:07

US3322314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:20:07

US3322314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:20:07

US3322314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:20:07

US3322314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:20:07

US3322314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Jan 2007'	System	11 Sep 2020 17:20:07

US3322314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '2007'	System	11 Sep 2020 17:20:07

US3322314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:20:07

US3322314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:20:07

US3322314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Sep 2020 19:13:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:13:41
Data point term sent to Coder	System	11 Sep 2020 17:21:52
User entered 'Codeine Allergy (Rash)'	(b) (4), (b) (6)	11 Sep 2020 17:20:51

US3322314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'un UNK 1975'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:20:51

US3322314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:20:51

US3322314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:20:51

US3322314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:20:51

US3322314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:21:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:20:51

US3322314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Jan 1975'	System	11 Sep 2020 17:20:51

US3322314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '1975'	System	11 Sep 2020 17:20:51

US3322314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:20:51

US3322314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:20:51

US3322314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User coded data point as SOC: Congenital, familial and genetic disorders, HLG: Cardiac and vascular disorders congenital, HLT: Cardiac malpositions congenital, PT: Dextrocardia, LLT: Dextrocardia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 17:22:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:22:49
Data point term sent to Coder	System	11 Sep 2020 17:21:52
User entered 'Dextrocardia'	(b) (4), (b) (6)	11 Sep 2020 17:21:17

US3322314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'un UNK 1986'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:21:17

US3322314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:21:17

US3322314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:21:17

US3322314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:21:17

US3322314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:21:17

US3322314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Jan 1986'	System	11 Sep 2020 17:21:17

US3322314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '1986'	System	11 Sep 2020 17:21:17

US3322314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:21:17

US3322314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:21:17

US3322314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 17:23:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:23:37
Data point term sent to Coder	System	11 Sep 2020 17:22:53
User entered 'Aortic Stenosis'	(b) (4), (b) (6)	11 Sep 2020 17:22:06

US3322314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered (b) (6) 1974'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:22:06

US3322314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:22:06

US3322314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:22:06

US3322314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Per DM CLR: Please review the stop date of this medical Condition as it was noted that a surgical procedure of AORTIC STENOSIS REPAIR SURGERY was performed in UN FEB 1985. Please review and update if appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:06:47
Query 'Per DM CLR: Please review the stop date of this medical Condition as it was noted that a surgical procedure of AORTIC STENOSIS REPAIR SURGERY was performed in UN FEB 1985. Please review and update if appropriate. Otherwise, clarify. ' answered with 'Updated per query. Thank you.' (Site from DM).		20 Oct 2020 17:23:51
User entered 'UN Feb 1985' reason for change: Data Entry Error		20 Oct 2020 17:23:37
User opened query 'Per DM CLR: Please review the stop date of this medical Condition as it was noted that a surgical procedure of AORTIC STENOSIS REPAIR SURGERY was performed in UN FEB 1985. Please review and update if appropriate. Otherwise, clarify. ' (Site from DM).		20 Oct 2020 14:32:29
User entered 'un Feb 1986'		11 Sep 2020 17:22:06

US3322314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:22:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:22:06

US3322314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered (b) (6) 1974'	System	11 Sep 2020 17:22:06

US3322314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '1974'	System	11 Sep 2020 17:22:06

US3322314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Feb 1985'	System	20 Oct 2020 17:23:37
User entered 'Feb 1986'	System	11 Sep 2020 17:22:06

US3322314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '1985'	System	20 Oct 2020 17:23:37
User entered '1986'	System	11 Sep 2020 17:22:06

US3322314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Aortic therapeutic procedures, PT: Aortic surgery, LLT: Aortic surgery - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	21 Sep 2020 22:52:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:52:51
Data point term sent to Coder	System	11 Sep 2020 17:22:54
User entered 'Aortic Stenosis repair Surgery'	(b) (4), (b) (6)	11 Sep 2020 17:22:31

US3322314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'un Feb 1985'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:22:31

US3322314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:22:31

US3322314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:22:31

US3322314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'un Feb 1985'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:22:31

US3322314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (u) (4), (b) (6)	11 Sep 2020 17:22:31

US3322314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Feb 1985'	System	11 Sep 2020 17:22:31

US3322314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '1985'	System	11 Sep 2020 17:22:31

US3322314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Feb 1985'	System	11 Sep 2020 17:22:31

US3322314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '1985'	System	11 Sep 2020 17:22:31

US3322314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Arteriosclerosis coronary artery, LLT: Coronary atherosclerosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 17:24:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 17:24:38
Data point term sent to Coder	System	11 Sep 2020 17:23:57
User entered 'Coronary Atherosclerosis'	(b) (4), (b) (6)	11 Sep 2020 17:23:06

US3322314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '23 Aug 2018'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:23:06

US3322314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:23:06

US3322314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:23:06

US3322314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:23:06

US3322314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:23:06

US3322314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Aug 2018'	System	11 Sep 2020 17:23:06

US3322314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '2018'	System	11 Sep 2020 17:23:06

US3322314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:23:06

US3322314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:23:06

US3322314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 17:24:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:24:35
Data point term sent to Coder	System	11 Sep 2020 17:24:00
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	11 Sep 2020 17:23:33

US3322314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '23 Aug 2018'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:23:33

US3322314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:23:33

US3322314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:23:33

US3322314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:23:33

US3322314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:23:33

US3322314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Aug 2018'	System	11 Sep 2020 17:23:33

US3322314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '2018'	System	11 Sep 2020 17:23:33

US3322314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:23:33

US3322314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	11 Sep 2020 17:23:33

US3322314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac disorders, signs and symptoms NEC, HLT: Cardiac signs and symptoms NEC, PT: Palpitations, LLT: Palpitation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	30 Oct 2020 21:14:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:14:13
Data point term sent to Coder	System	30 Oct 2020 21:04:20
User entered 'palpitation'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:04:19

US3322314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'un UNK 2017'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:04:19

US3322314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:04:19

US3322314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:04:19

US3322314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'un UNK 2017'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:04:19

US3322314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:04:19

US3322314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Jan 2017'	System	30 Oct 2020 21:04:19

US3322314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '2017'	System	30 Oct 2020 21:04:19

US3322314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'Jan 2017'	System	30 Oct 2020 21:04:19

US3322314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '2017'	System	30 Oct 2020 21:04:19

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Per CDM: Please record using 24 hr format' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 11:55:28
Query 'Per CDM: Please record using 24 hr format' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 03:44:46
User entered '08:50' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 03:44:33
User opened query 'Per CDM: Please record using 24 hr format' (Site from DM).	(b) (4), (b) (6)	26 Sep 2020 13:49:58
Query 'Per CDM: Please confirm if time 08:50 is AM or PM. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	26 Sep 2020 13:49:36
User opened query 'Per CDM: Please confirm if time 08:50 is AM or PM. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:19:16
User entered '8:50'	(b) (4), (b) (6)	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '11 Sep 2020 08:50'	System	27 Sep 2020 03:44:33
User entered '11 Sep 2020 8:50'	System	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '67' in	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42
DataPoint set to visible.	System	11 Sep 2020 15:59:57

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '190.2' lb	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42
DataPoint set to visible.	System	11 Sep 2020 15:59:57

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '29.85182'	System	11 Sep 2020 17:24:42
DataPoint set to visible.	System	11 Sep 2020 15:59:57

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'kg/m2'	System	11 Sep 2020 17:24:42
DataPoint set to visible.	System	11 Sep 2020 15:59:57

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'bpm'	System	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'breaths/min'	System	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'mmHg'	System	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'mmHg'	System	11 Sep 2020 17:24:42

US3322314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00

US3322314

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:24:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:25:15
User entered 'Yes (Y)' reason for change: Data Entry Error	System	11 Sep 2020 17:25:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 17:25:15
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:24:48
	(b) (4), (b) (6)	11 Sep 2020 17:24:48

US3322314

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:24:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:24:48

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:27:45
User entered 'No (N)' reason for change: Data Entry Error	System	11 Sep 2020 17:27:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
User entered empty.	System	11 Sep 2020 17:27:05
	(b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:27:45
User entered 'No (N)' reason for change: Data Entry Error	System	11 Sep 2020 17:27:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
User entered empty.	System	11 Sep 2020 17:27:05
	(b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:27:45
User entered 'No (N)' reason for change: Data Entry Error	System	11 Sep 2020 17:27:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
User entered empty.	System	11 Sep 2020 17:27:05
	(b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:27:45
User entered 'No (N)' reason for change: Data Entry Error	System	11 Sep 2020 17:27:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
User entered empty.	System	11 Sep 2020 17:27:05
	(b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:27:45
User entered 'No (N)' reason for change: Data Entry Error	System	11 Sep 2020 17:27:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
User entered empty.	System	11 Sep 2020 17:27:05
	(b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:27:45
User entered 'No (N)' reason for change: Data Entry Error	System	11 Sep 2020 17:27:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
User entered empty.	System	11 Sep 2020 17:27:05
	(b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:27:45
User entered 'No (N)' reason for change: Data Entry Error	System	11 Sep 2020 17:27:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
User entered empty.	System	11 Sep 2020 17:27:05
	(b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:27:45
User entered 'No (N)' reason for change: Data Entry Error	System	11 Sep 2020 17:27:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
User entered empty.	System	11 Sep 2020 17:27:05
	(b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:27:45
User entered 'No (N)' reason for change: Data Entry Error	System	11 Sep 2020 17:27:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
User entered empty.	System	11 Sep 2020 17:27:05
	(b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 17:27:45
User entered 'No (N)' reason for change: Data Entry Error	System	11 Sep 2020 17:27:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
User entered empty.	System	11 Sep 2020 17:27:05
	(b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Subject is a school teacher who is working from home. Face to face teaching will be starting in middle of Oct.'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (D) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 20:25:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'His partner is a medical technologist who is working at hospital 5 days a week. The subject goes to the gym 3 times a week, groceries lik 2 times a week, and dinning outside 2 times a week.'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:27:05

US3322314

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:23:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:28:24

US3322314

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:23:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:28:24

US3322314

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:23:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:28:24

US3322314

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'VISIT1'	System	11 Sep 2020 17:28:24

US3322314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:22:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 15:04:20

US3322314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:30

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:22:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '146219'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 15:04:20

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:30

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:22:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 15:04:20

US3322314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:30

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:22:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:30:10

US3322314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:30

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:22:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:30:10

US3322314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:30

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:22:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:30:10

US3322314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:30

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:22:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:30:10

US3322314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:22:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:30:10

US3322314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:30

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:22:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	26 Sep 2020 18:35:23
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 06:08:25
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:08:24

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User accepted default value 'Pre-Dose (PREDOSE)'		11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 14:42:32
Query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 15:26:47
User entered '08:57' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 15:26:42
User opened query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 21:24:06
User entered '8:57'		11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '11 Sep 2020 08:57'	System	23 Oct 2020 15:26:42
User entered '11 Sep 2020 8:57'	System	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (u) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '76'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'bpm'	System	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '15'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'breaths/min'	System	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '105'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'mmHg'	System	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '68'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'mmHg'	System	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User accepted default value 'Post-Dose (POSTDOSE)'		11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11:23'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '11 Sep 2020 11:23'	System	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '73'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'bpm'	System	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '17'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'breaths/min'	System	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '115'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'mmHg'	System	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '72'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'mmHg'	System	11 Sep 2020 17:32:22

US3322314

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:36

US3322314

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:24:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:36

US3322314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 16:00:21

US3322314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 16:00:21

US3322314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 16:00:21

US3322314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 16:00:21

US3322314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 Sep 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 16:00:21

US3322314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '10:50'	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 16:00:21

US3322314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '11 Sep 2020 10:50'	System	11 Sep 2020 16:00:21

US3322314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) Frances Saubon (b) (4) (b) (4)	11 Sep 2020 16:00:21

US3322314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:23
User entered 'ONCE'	System	11 Sep 2020 16:00:21

US3322314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 16:00:21

US3322314

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:56

US3322314

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:56

US3322314

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '10:17'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:32:56

US3322314

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '11 Sep 2020 10:17'	System	11 Sep 2020 17:32:56

US3322314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:08:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:28

US3322314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		11 Sep 2020 17:33:28

US3322314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:28

US3322314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:30

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '10:07'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:28

US3322314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '11 Sep 2020 10:07'	System	11 Sep 2020 17:33:28

US3322314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		11 Sep 2020 17:33:28

US3322314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:28

US3322314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:28

US3322314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered empty.	System	11 Sep 2020 17:33:28

US3322314

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 20:55:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:33:32

US3322314

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'I'	System	11 Sep 2020 17:33:32

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:22:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9e060cb5-44d6-4be5-9edf-9065ce03d300'	System	11 Sep 2020 16:23:07
User entered 'Yes (Y)'	System	11 Sep 2020 16:23:07

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:22:48', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9e060cb5-44d6-4be5-9edf-9065ce03d300'	System	11 Sep 2020 16:23:07
User entered '97.3'	System	11 Sep 2020 16:23:07

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:22:52', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9e060cb5-44d6-4be5-9edf-9065ce03d300'	System	11 Sep 2020 16:23:07
User entered 'No (N)'	System	11 Sep 2020 16:23:07

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:22:59', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9e060cb5-44d6-4be5-9edf-9065ce03d300'	System	11 Sep 2020 16:23:07
User entered '11 Sep 2020 11:22'	System	11 Sep 2020 16:23:07

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Sep 2020 11:10'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Sep 2020 13:40'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T21:22:03', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2751f56-1905-48c2-b45f-84c0407de2b9'	System	12 Sep 2020 02:27:18
User entered 'Yes (Y)'	System	12 Sep 2020 02:27:18

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T21:22:12', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2751f56-1905-48c2-b45f-84c0407de2b9' User entered '97.3'	System	12 Sep 2020 02:27:18
	System	12 Sep 2020 02:27:18

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T21:22:17', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2751f56-1905-48c2-b45f-84c0407de2b9'	System	12 Sep 2020 02:27:18
User entered 'No (N)'	System	12 Sep 2020 02:27:18

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T21:22:20', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2751f56-1905-48c2-b45f-84c0407de2b9'	System	12 Sep 2020 02:27:18
User entered '11 Sep 2020 21:22'	System	12 Sep 2020 02:27:18

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Sep 2020 14:35'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 2'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:05:17', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'c769f469-3c82-497b-bacf-0ebf3fb2c216'	System	13 Sep 2020 00:07:58
User entered 'Yes (Y)'	System	13 Sep 2020 00:07:58

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:05:22', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'c769f469-3c82-497b-bacf-0ebf3fb2c216'	System	13 Sep 2020 00:07:58
User entered '97.5'	System	13 Sep 2020 00:07:58

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:05:28', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'c769f469-3c82-497b-bacf-0ebf3fb2c216'	System	13 Sep 2020 00:07:58
User entered 'Yes (Y)'	System	13 Sep 2020 00:07:58

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient took medication for pain at the injection site, concomitant medications are entered' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 07:32:44
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:05:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'c769f469-3c82-497b-bacf-0ebf3fb2c216'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:38:03
User entered '1'	System	13 Sep 2020 00:07:58

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:05:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'c769f469-3c82-497b-bacf-0ebf3fb2c216' User entered '0'	System	13 Sep 2020 00:07:58
	System	13 Sep 2020 00:07:58

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:06:02', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'c769f469-3c82-497b-bacf-0ebf3fb2c216'	System	13 Sep 2020 00:07:58
User entered '12 Sep 2020 19:06'	System	13 Sep 2020 00:07:58

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 3'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:16:46', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7d4f5b1a-5c2f-468f-bd02-db06c9949f5c'	System	13 Sep 2020 23:17:06
User entered 'Yes (Y)'	System	13 Sep 2020 23:17:06

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:16:52', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7d4f5b1a-5c2f-468f-bd02-db06c9949f5c'	System	13 Sep 2020 23:17:06
User entered '97.3'	System	13 Sep 2020 23:17:06

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:16:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7d4f5b1a-5c2f-468f-bd02-db06c9949f5c'	System	13 Sep 2020 23:17:06
User entered 'No (N)'	System	13 Sep 2020 23:17:06

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:17:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7d4f5b1a-5c2f-468f-bd02-db06c9949f5c'	System	13 Sep 2020 23:17:06
User entered '13 Sep 2020 18:17'	System	13 Sep 2020 23:17:06

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 4'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:51:53', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0c84e240-2bd7-4360-819a-4805e7d9f2f0'	System	15 Sep 2020 03:52:12
User entered 'Yes (Y)'	System	15 Sep 2020 03:52:12

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:51:59', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0c84e240-2bd7-4360-819a-4805e7d9f2f0'	System	15 Sep 2020 03:52:12
User entered '97.3'	System	15 Sep 2020 03:52:12

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:04', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0c84e240-2bd7-4360-819a-4805e7d9f2f0'	System	15 Sep 2020 03:52:12
User entered 'No (N)'	System	15 Sep 2020 03:52:12

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:08', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0c84e240-2bd7-4360-819a-4805e7d9f2f0'	System	15 Sep 2020 03:52:12
User entered '14 Sep 2020 22:52'	System	15 Sep 2020 03:52:12

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 5'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:02:14', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7cbed7cc-9192-4681-9573-26f9df133a66'	System	15 Sep 2020 21:02:37
User entered 'Yes (Y)'	System	15 Sep 2020 21:02:37

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:02:19', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7cbed7cc-9192-4681-9573-26f9df133a66'	System	15 Sep 2020 21:02:37
User entered '98.0'	System	15 Sep 2020 21:02:37

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:02:23', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7cbed7cc-9192-4681-9573-26f9df133a66'	System	15 Sep 2020 21:02:37
User entered 'No (N)'	System	15 Sep 2020 21:02:37

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:02:30', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7cbed7cc-9192-4681-9573-26f9df133a66'	System	15 Sep 2020 21:02:37
User entered '15 Sep 2020 16:02'	System	15 Sep 2020 21:02:37

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 6'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:45:12', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7f44abf0-cc77-4f2d-8dd1-ddc1d7ef7ba2'	System	17 Sep 2020 01:45:36
User entered 'Yes (Y)'	System	17 Sep 2020 01:45:36

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:45:20', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7f44abf0-cc77-4f2d-8dd1-ddc1d7ef7ba2'	System	17 Sep 2020 01:45:36
User entered '98.1'	System	17 Sep 2020 01:45:36

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:45:24', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7f44abf0-cc77-4f2d-8dd1-ddc1d7ef7ba2'	System	17 Sep 2020 01:45:36
User entered 'No (N)'	System	17 Sep 2020 01:45:36

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:45:30', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '7f44abf0-cc77-4f2d-8dd1-ddc1d7ef7ba2'	System	17 Sep 2020 01:45:36
User entered '16 Sep 2020 20:45'	System	17 Sep 2020 01:45:36

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 7'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:57:50', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9c9d6d6f-1731-47ad-b651-87267b1a40a6'	System	17 Sep 2020 21:58:09
User entered 'Yes (Y)'	System	17 Sep 2020 21:58:09

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:57:55', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9c9d6d6f-1731-47ad-b651-87267b1a40a6'	System	17 Sep 2020 21:58:09
User entered '98.1'	System	17 Sep 2020 21:58:09

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:57:59', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9c9d6d6f-1731-47ad-b651-87267b1a40a6'	System	17 Sep 2020 21:58:09
User entered 'No (N)'	System	17 Sep 2020 21:58:09

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:04', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9c9d6d6f-1731-47ad-b651-87267b1a40a6'	System	17 Sep 2020 21:58:09
User entered '17 Sep 2020 16:58'	System	17 Sep 2020 21:58:09

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:23:14', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a2627800-f685-4a83-8d27-1ac19111e231'	System	11 Sep 2020 16:24:07
User entered 'None (1)'	System	11 Sep 2020 16:24:07

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:23:37', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a2627800-f685-4a83-8d27-1ac19111e231'	System	11 Sep 2020 16:24:07
User entered 'No (N)'	System	11 Sep 2020 16:24:07

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:23:43', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a2627800-f685-4a83-8d27-1ac19111e231'	System	11 Sep 2020 16:24:07
User entered 'No (N)'	System	11 Sep 2020 16:24:07

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:23:59', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a2627800-f685-4a83-8d27-1ac19111e231'	System	11 Sep 2020 16:24:07
User entered 'None (1)'	System	11 Sep 2020 16:24:07

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:24:02', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a2627800-f685-4a83-8d27-1ac19111e231'	System	11 Sep 2020 16:24:07
User entered '11 Sep 2020 11:24'	System	11 Sep 2020 16:24:07

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Sep 2020 11:10'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Sep 2020 13:40'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T21:22:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'dc9dc9fc-711d-48b6-9419-1a2dd0b678cb'	System	12 Sep 2020 02:26:03
User entered 'None (1)'	System	12 Sep 2020 02:26:03

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T21:22:39', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'dc9dc9fc-711d-48b6-9419-1a2dd0b678cb'	System	12 Sep 2020 02:26:03
User entered 'No (N)'	System	12 Sep 2020 02:26:03

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T21:22:42', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'dc9dc9fc-711d-48b6-9419-1a2dd0b678cb'	System	12 Sep 2020 02:26:03
User entered 'No (N)'	System	12 Sep 2020 02:26:03

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T21:22:49', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'dc9dc9fc-711d-48b6-9419-1a2dd0b678cb'	System	12 Sep 2020 02:26:03
User entered 'None (1)'	System	12 Sep 2020 02:26:03

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T21:22:54', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'dc9dc9fc-711d-48b6-9419-1a2dd0b678cb'	System	12 Sep 2020 02:26:03
User entered '11 Sep 2020 21:22'	System	12 Sep 2020 02:26:03

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Sep 2020 14:35'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 2'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:06:24', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '56a749a4-c501-4db9-9b49-8d9e97edd5b7'	System	13 Sep 2020 00:08:24
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	13 Sep 2020 00:08:24

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:06:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '56a749a4-c501-4db9-9b49-8d9e97edd5b7'	System	13 Sep 2020 00:08:24
User entered 'No (N)'	System	13 Sep 2020 00:08:24

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:06:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '56a749a4-c501-4db9-9b49-8d9e97edd5b7'	System	13 Sep 2020 00:08:24
User entered 'Yes (Y)'	System	13 Sep 2020 00:08:24

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:06:54', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '56a749a4-c501-4db9-9b49-8d9e97edd5b7'	System	13 Sep 2020 00:08:24
User entered '2'	System	13 Sep 2020 00:08:24

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:07:02', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '56a749a4-c501-4db9-9b49-8d9e97edd5b7'	System	13 Sep 2020 00:08:24
User entered 'None (1)'	System	13 Sep 2020 00:08:24

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:07:05', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '56a749a4-c501-4db9-9b49-8d9e97edd5b7'	System	13 Sep 2020 00:08:24
User entered '12 Sep 2020 19:07'	System	13 Sep 2020 00:08:24

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 3'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:17:12', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '798146ed-3613-4b9c-822b-d467fdb170ed'	System	13 Sep 2020 23:17:57
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 23:17:57

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:17:19', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '798146ed-3613-4b9c-822b-d467fdb170ed'	System	13 Sep 2020 23:17:57
User entered 'No (N)'	System	13 Sep 2020 23:17:57

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:17:25', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '798146ed-3613-4b9c-822b-d467fdb170ed'	System	13 Sep 2020 23:17:57
User entered 'Yes (Y)'	System	13 Sep 2020 23:17:57

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:17:42', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '798146ed-3613-4b9c-822b-d467fdb170ed'	System	13 Sep 2020 23:17:57
User entered '1'	System	13 Sep 2020 23:17:57

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:17:49', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '798146ed-3613-4b9c-822b-d467fdb170ed'	System	13 Sep 2020 23:17:57
User entered 'None (1)'	System	13 Sep 2020 23:17:57

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:17:53', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '798146ed-3613-4b9c-822b-d467fdb170ed'	System	13 Sep 2020 23:17:57
User entered '13 Sep 2020 18:17'	System	13 Sep 2020 23:17:57

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 4'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:14', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6c7ba1c3-7738-49c8-bbe0-c81657d8eb67'	System	15 Sep 2020 03:52:31
User entered 'None (1)'	System	15 Sep 2020 03:52:31

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:18', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6c7ba1c3-7738-49c8-bbe0-c81657d8eb67'	System	15 Sep 2020 03:52:31
User entered 'No (N)'	System	15 Sep 2020 03:52:31

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:21', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6c7ba1c3-7738-49c8-bbe0-c81657d8eb67'	System	15 Sep 2020 03:52:31
User entered 'No (N)'	System	15 Sep 2020 03:52:31

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:26', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6c7ba1c3-7738-49c8-bbe0-c81657d8eb67'	System	15 Sep 2020 03:52:31
User entered 'None (1)'	System	15 Sep 2020 03:52:31

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:28', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6c7ba1c3-7738-49c8-bbe0-c81657d8eb67'	System	15 Sep 2020 03:52:31
User entered '14 Sep 2020 22:52'	System	15 Sep 2020 03:52:31

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 5'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:02:39', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e77fd2d0-dbf8-4831-9285-18a5a69ccb9a'	System	15 Sep 2020 21:02:58
User entered 'None (1)'	System	15 Sep 2020 21:02:58

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:02:42', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e77fd2d0-dbf8-4831-9285-18a5a69ccb9a'	System	15 Sep 2020 21:02:58
User entered 'No (N)'	System	15 Sep 2020 21:02:58

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:02:45', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e77fd2d0-dbf8-4831-9285-18a5a69ccb9a'	System	15 Sep 2020 21:02:58
User entered 'No (N)'	System	15 Sep 2020 21:02:58

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:02:49', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e77fd2d0-dbf8-4831-9285-18a5a69ccb9a'	System	15 Sep 2020 21:02:58
User entered 'None (1)'	System	15 Sep 2020 21:02:58

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:02:54', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e77fd2d0-dbf8-4831-9285-18a5a69ccb9a'	System	15 Sep 2020 21:02:58
User entered '15 Sep 2020 16:02'	System	15 Sep 2020 21:02:58

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 6'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:45:43', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '70ad1a8e-48c1-4efb-9d17-81fed83609ba'	System	17 Sep 2020 01:46:13
User entered 'None (1)'	System	17 Sep 2020 01:46:13

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:45:48', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '70ad1a8e-48c1-4efb-9d17-81fed83609ba'	System	17 Sep 2020 01:46:13
User entered 'No (N)'	System	17 Sep 2020 01:46:13

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:45:54', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '70ad1a8e-48c1-4efb-9d17-81fed83609ba'	System	17 Sep 2020 01:46:13
User entered 'No (N)'	System	17 Sep 2020 01:46:13

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:45:58', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '70ad1a8e-48c1-4efb-9d17-81fed83609ba'	System	17 Sep 2020 01:46:13
User entered 'None (1)'	System	17 Sep 2020 01:46:13

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:46:09', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '70ad1a8e-48c1-4efb-9d17-81fed83609ba'	System	17 Sep 2020 01:46:13
User entered '16 Sep 2020 20:46'	System	17 Sep 2020 01:46:13

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 7'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:10', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '3813e636-bcef-429f-b4e2-8f921a679d7d'	System	17 Sep 2020 21:58:28
User entered 'None (1)'	System	17 Sep 2020 21:58:28

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:13', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '3813e636-bcef-429f-b4e2-8f921a679d7d'	System	17 Sep 2020 21:58:28
User entered 'No (N)'	System	17 Sep 2020 21:58:28

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:17', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '3813e636-bcef-429f-b4e2-8f921a679d7d'	System	17 Sep 2020 21:58:28
User entered 'No (N)'	System	17 Sep 2020 21:58:28

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:22', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '3813e636-bcef-429f-b4e2-8f921a679d7d'	System	17 Sep 2020 21:58:28
User entered 'None (1)'	System	17 Sep 2020 21:58:28

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:26', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '3813e636-bcef-429f-b4e2-8f921a679d7d' User entered '17 Sep 2020 16:58'	System	17 Sep 2020 21:58:28
	System	17 Sep 2020 21:58:28

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:24:10', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0968cacf-13aa-4532-8fbb-fbaaad7f4fc3'	System	11 Sep 2020 16:25:16
User entered 'None (0)'	System	11 Sep 2020 16:25:16

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:24:39', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0968cacf-13aa-4532-8fbb-fbaaad7f4fc3'	System	11 Sep 2020 16:25:16
User entered 'No interference with activity (1)'	System	11 Sep 2020 16:25:16

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:24:44', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0968cacf-13aa-4532-8fbb-fbaaad7f4fc3' User entered 'None (0)'	System	11 Sep 2020 16:25:16
	System	11 Sep 2020 16:25:16

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:24:47', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0968cacf-13aa-4532-8fbb-fbaaad7f4fc3' User entered 'None (0)'	System	11 Sep 2020 16:25:16
	System	11 Sep 2020 16:25:16

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:24:51', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0968cacf-13aa-4532-8fbb-fbaaad7f4fc3'	System	11 Sep 2020 16:25:16
User entered 'None (0)'	System	11 Sep 2020 16:25:16

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:24:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0968cacf-13aa-4532-8fbb-fbaaad7f4fc3'	System	11 Sep 2020 16:25:16
User entered 'None (0)'	System	11 Sep 2020 16:25:16

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:25:03', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0968cacf-13aa-4532-8fbb-fbaaad7f4fc3'	System	11 Sep 2020 16:25:16
User entered 'No (N)'	System	11 Sep 2020 16:25:16

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T11:25:10', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '0968cacf-13aa-4532-8fbb-fbaaad7f4fc3'	System	11 Sep 2020 16:25:16
User entered '11 Sep 2020 11:25'	System	11 Sep 2020 16:25:16

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Sep 2020 11:10'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Sep 2020 13:40'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T14:35:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a1f6ed26-ffae-4c25-ba73-4278b963bc0a'	System	11 Sep 2020 19:36:43
User entered 'None (0)'	System	11 Sep 2020 19:36:43

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T14:36:02', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a1f6ed26-ffae-4c25-ba73-4278b963bc0a'	System	11 Sep 2020 19:36:43
User entered 'No interference with activity (1)'	System	11 Sep 2020 19:36:43

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T14:36:05', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a1f6ed26-ffae-4c25-ba73-4278b963bc0a' User entered 'None (0)'	System	11 Sep 2020 19:36:43
	System	11 Sep 2020 19:36:43

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T14:36:08', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a1f6ed26-ffae-4c25-ba73-4278b963bc0a' User entered 'None (0)'	System	11 Sep 2020 19:36:43
	System	11 Sep 2020 19:36:43

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T14:36:14', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a1f6ed26-ffae-4c25-ba73-4278b963bc0a'	System	11 Sep 2020 19:36:43
User entered 'None (0)'	System	11 Sep 2020 19:36:43

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T14:36:16', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a1f6ed26-ffae-4c25-ba73-4278b963bc0a'	System	11 Sep 2020 19:36:43
User entered 'None (0)'	System	11 Sep 2020 19:36:43

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T14:36:20', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a1f6ed26-ffae-4c25-ba73-4278b963bc0a'	System	11 Sep 2020 19:36:43
User entered 'No (N)'	System	11 Sep 2020 19:36:43

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-11T14:36:22', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a1f6ed26-ffae-4c25-ba73-4278b963bc0a'	System	11 Sep 2020 19:36:43
User entered '11 Sep 2020 14:36'	System	11 Sep 2020 19:36:43

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Sep 2020 14:35'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 2'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:07:10', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '4d54cdda-bd96-45b3-9a01-15f8cc2cdea5'	System	13 Sep 2020 00:09:11
User entered 'None (0)'	System	13 Sep 2020 00:09:11

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:07:15', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '4d54cdda-bd96-45b3-9a01-15f8cc2cdea5'	System	13 Sep 2020 00:09:11
User entered 'Some interference with activity (2)'	System	13 Sep 2020 00:09:11

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:07:20', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '4d54cdda-bd96-45b3-9a01-15f8cc2cdea5'	System	13 Sep 2020 00:09:11
User entered 'Some interference with activity (2)'	System	13 Sep 2020 00:09:11

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:07:25', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '4d54cdda-bd96-45b3-9a01-15f8cc2cdea5'	System	13 Sep 2020 00:09:11
User entered 'Some interference with activity (2)'	System	13 Sep 2020 00:09:11

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:07:28', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '4d54cdda-bd96-45b3-9a01-15f8cc2cdea5'	System	13 Sep 2020 00:09:11
User entered 'None (0)'	System	13 Sep 2020 00:09:11

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:07:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '4d54cdda-bd96-45b3-9a01-15f8cc2cdea5'	System	13 Sep 2020 00:09:11
User entered 'Some interference with activity not requiring medical attention (2)'	System	13 Sep 2020 00:09:11

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:07:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '4d54cdda-bd96-45b3-9a01-15f8cc2cdea5'	System	13 Sep 2020 00:09:11
User entered 'No (N)'	System	13 Sep 2020 00:09:11

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-12T19:07:45', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '4d54cdda-bd96-45b3-9a01-15f8cc2cdea5'	System	13 Sep 2020 00:09:11
User entered '12 Sep 2020 19:07'	System	13 Sep 2020 00:09:11

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 3'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:17:58', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd30fbded-d06a-48f3-8f2f-bb0b74d72836'	System	13 Sep 2020 23:18:30
User entered 'None (0)'	System	13 Sep 2020 23:18:30

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:18:05', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd30fbded-d06a-48f3-8f2f-bb0b74d72836'	System	13 Sep 2020 23:18:30
User entered 'None (0)'	System	13 Sep 2020 23:18:30

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:18:09', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd30fbded-d06a-48f3-8f2f-bb0b74d72836'	System	13 Sep 2020 23:18:30
User entered 'No interference with activity (1)'	System	13 Sep 2020 23:18:30

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:18:13', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd30fbded-d06a-48f3-8f2f-bb0b74d72836'	System	13 Sep 2020 23:18:30
User entered 'No interference with activity (1)'	System	13 Sep 2020 23:18:30

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:18:15', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd30fbded-d06a-48f3-8f2f-bb0b74d72836'	System	13 Sep 2020 23:18:30
User entered 'None (0)'	System	13 Sep 2020 23:18:30

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:18:18', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd30fbded-d06a-48f3-8f2f-bb0b74d72836'	System	13 Sep 2020 23:18:30
User entered 'None (0)'	System	13 Sep 2020 23:18:30

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:18:24', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd30fbded-d06a-48f3-8f2f-bb0b74d72836'	System	13 Sep 2020 23:18:30
User entered 'No (N)'	System	13 Sep 2020 23:18:30

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-13T18:18:26', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd30fbded-d06a-48f3-8f2f-bb0b74d72836'	System	13 Sep 2020 23:18:30
User entered '13 Sep 2020 18:18'	System	13 Sep 2020 23:18:30

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 4'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:37', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8e99ac11-5462-4e0c-b78e-bd33c137efd4'	System	15 Sep 2020 03:53:08
User entered 'None (0)'	System	15 Sep 2020 03:53:08

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:39', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8e99ac11-5462-4e0c-b78e-bd33c137efd4'	System	15 Sep 2020 03:53:08
User entered 'None (0)'	System	15 Sep 2020 03:53:08

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:44', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8e99ac11-5462-4e0c-b78e-bd33c137efd4'	System	15 Sep 2020 03:53:08
User entered 'None (0)'	System	15 Sep 2020 03:53:08

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:50', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8e99ac11-5462-4e0c-b78e-bd33c137efd4'	System	15 Sep 2020 03:53:08
User entered 'None (0)'	System	15 Sep 2020 03:53:08

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:53', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8e99ac11-5462-4e0c-b78e-bd33c137efd4'	System	15 Sep 2020 03:53:08
User entered 'None (0)'	System	15 Sep 2020 03:53:08

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:52:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8e99ac11-5462-4e0c-b78e-bd33c137efd4'	System	15 Sep 2020 03:53:08
User entered 'None (0)'	System	15 Sep 2020 03:53:08

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:53:02', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8e99ac11-5462-4e0c-b78e-bd33c137efd4'	System	15 Sep 2020 03:53:08
User entered 'No (N)'	System	15 Sep 2020 03:53:08

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-14T22:53:05', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8e99ac11-5462-4e0c-b78e-bd33c137efd4'	System	15 Sep 2020 03:53:08
User entered '14 Sep 2020 22:53'	System	15 Sep 2020 03:53:08

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 5'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:02:58', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a4df76b7-0407-41d3-a9c2-fe6b834979c9'	System	15 Sep 2020 21:03:20
User entered 'None (0)'	System	15 Sep 2020 21:03:20

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:03:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a4df76b7-0407-41d3-a9c2-fe6b834979c9'	System	15 Sep 2020 21:03:20
User entered 'None (0)'	System	15 Sep 2020 21:03:20

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:03:03', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a4df76b7-0407-41d3-a9c2-fe6b834979c9'	System	15 Sep 2020 21:03:20
User entered 'None (0)'	System	15 Sep 2020 21:03:20

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:03:05', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a4df76b7-0407-41d3-a9c2-fe6b834979c9'	System	15 Sep 2020 21:03:20
User entered 'None (0)'	System	15 Sep 2020 21:03:20

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:03:07', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a4df76b7-0407-41d3-a9c2-fe6b834979c9'	System	15 Sep 2020 21:03:20
User entered 'None (0)'	System	15 Sep 2020 21:03:20

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:03:10', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a4df76b7-0407-41d3-a9c2-fe6b834979c9'	System	15 Sep 2020 21:03:20
User entered 'None (0)'	System	15 Sep 2020 21:03:20

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:03:12', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a4df76b7-0407-41d3-a9c2-fe6b834979c9'	System	15 Sep 2020 21:03:20
User entered 'No (N)'	System	15 Sep 2020 21:03:20

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-15T16:03:14', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a4df76b7-0407-41d3-a9c2-fe6b834979c9'	System	15 Sep 2020 21:03:20
User entered '15 Sep 2020 16:03'	System	15 Sep 2020 21:03:20

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 6'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:46:14', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5dbdaf68-db92-4d79-826a-97a5eebeb4fb' User entered 'None (0)'	System	17 Sep 2020 01:46:45
	System	17 Sep 2020 01:46:45

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:46:16', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5dbdaf68-db92-4d79-826a-97a5eebeb4fb' User entered 'None (0)'	System	17 Sep 2020 01:46:45
	System	17 Sep 2020 01:46:45

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:46:19', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5dbdaf68-db92-4d79-826a-97a5eebeb4fb'	System	17 Sep 2020 01:46:45
User entered 'None (0)'	System	17 Sep 2020 01:46:45

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:46:24', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5dbdaf68-db92-4d79-826a-97a5eebeb4fb' User entered 'None (0)'	System	17 Sep 2020 01:46:45
	System	17 Sep 2020 01:46:45

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:46:31', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5dbdaf68-db92-4d79-826a-97a5eebeb4fb' User entered 'None (0)'	System	17 Sep 2020 01:46:45
	System	17 Sep 2020 01:46:45

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:46:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5dbdaf68-db92-4d79-826a-97a5eebeb4fb' User entered 'None (0)'	System	17 Sep 2020 01:46:45
	System	17 Sep 2020 01:46:45

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:46:39', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5dbdaf68-db92-4d79-826a-97a5eebeb4fb'	System	17 Sep 2020 01:46:45
User entered 'No (N)'	System	17 Sep 2020 01:46:45

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-16T20:46:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5dbdaf68-db92-4d79-826a-97a5eebeb4fb'	System	17 Sep 2020 01:46:45
User entered '16 Sep 2020 20:46'	System	17 Sep 2020 01:46:45

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 7'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:31', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8233bf09-29f9-4d69-a27a-5ab82d68e618'	System	17 Sep 2020 21:58:58
User entered 'None (0)'	System	17 Sep 2020 21:58:58

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8233bf09-29f9-4d69-a27a-5ab82d68e618'	System	17 Sep 2020 21:58:58
User entered 'None (0)'	System	17 Sep 2020 21:58:58

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:35', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8233bf09-29f9-4d69-a27a-5ab82d68e618'	System	17 Sep 2020 21:58:58
User entered 'None (0)'	System	17 Sep 2020 21:58:58

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:38', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8233bf09-29f9-4d69-a27a-5ab82d68e618'	System	17 Sep 2020 21:58:58
User entered 'None (0)'	System	17 Sep 2020 21:58:58

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:40', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8233bf09-29f9-4d69-a27a-5ab82d68e618'	System	17 Sep 2020 21:58:58
User entered 'None (0)'	System	17 Sep 2020 21:58:58

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:42', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8233bf09-29f9-4d69-a27a-5ab82d68e618'	System	17 Sep 2020 21:58:58
User entered 'None (0)'	System	17 Sep 2020 21:58:58

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:47', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8233bf09-29f9-4d69-a27a-5ab82d68e618'	System	17 Sep 2020 21:58:58
User entered 'No (N)'	System	17 Sep 2020 21:58:58

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-09-17T16:58:51', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8233bf09-29f9-4d69-a27a-5ab82d68e618'	System	17 Sep 2020 21:58:58
User entered '17 Sep 2020 16:58'	System	17 Sep 2020 21:58:58

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 16:00:21

US3322314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:10:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 17:08:02

US3322314

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:10:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '18 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 17:08:02

US3322314

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:10:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 17:08:02

US3322314

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:10:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 17:08:02

US3322314

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:10:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 17:08:07

US3322314

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '1'	System	18 Sep 2020 17:08:07

US3322314

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:19:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:11:20

US3322314

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:19:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '28 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:11:20

US3322314

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:19:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:11:20

US3322314

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:19:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:11:20

US3322314

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:20:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:11:24

US3322314

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'I'	System	29 Sep 2020 17:11:24

US3322314

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:20:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 14:39:32

US3322314

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:20:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '3 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 14:39:32

US3322314

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:20:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 14:39:32

US3322314

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:20:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 14:39:32

US3322314

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:20:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 14:39:35

US3322314

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'I'	System	06 Oct 2020 14:39:35

US3322314

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:20:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:33:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:20:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:33:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:20:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:33:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'VISIT2'	System	09 Oct 2020 21:33:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User accepted default value 'Pre-Dose (PREDOSE)'		09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '10:30'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '9 Oct 2020 10:30'	System	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '96.9' F	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '73'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'bpm'	System	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '14'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'breaths/min'	System	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '123'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'mmHg'	System	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '71'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'mmHg'	System	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User accepted default value 'Post-Dose (POSTDOSE)'		09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11:55'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '9 Oct 2020 11:55'	System	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '76'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'bpm'	System	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '13'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'breaths/min'	System	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '123'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'mmHg'	System	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '62'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'mmHg'	System	09 Oct 2020 21:34:24

US3322314

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:59

US3322314

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:34:59

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Oct 2020 16:33:21

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Oct 2020 16:33:21

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Oct 2020 16:33:21

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 16:33:21

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:32:02
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' answered with 'Updated' (Site from DM).		15 Oct 2020 17:12:12
User entered '09 Oct 2020' reason for change: Data Entry Error		15 Oct 2020 17:12:08
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' (Site from DM).		15 Oct 2020 14:22:26
User entered '9 Oct 2020'	Frances Saubon (b) (4) (b) (4)	09 Oct 2020 16:33:21

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11:25'	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Oct 2020 16:33:21

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '09 Oct 2020 11:25'	System	15 Oct 2020 17:12:08
User entered '9 Oct 2020 11:25'	System	09 Oct 2020 16:33:21

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Oct 2020 16:33:21

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:21:53
User entered 'ONCE'	System	09 Oct 2020 16:33:21

US3322314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 16:33:21

US3322314

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:23:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:35:48

US3322314

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:23:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Per GCL Lab Reconciliation: Sample dated 09Oct2020 is recorded under Visit2 Day29 visit in EDC, however a sample dated 08Oct2020 was received in PPD Central lab. Please reconcile the correct date and update if applicable. Else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:51:44
User entered '09 Oct 2020' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	11 Nov 2020 15:14:36
Query 'Per GCL Lab Reconciliation: Sample dated 09Oct2020 is recorded under Visit2 Day29 visit in EDC, however a sample dated 08Oct2020 was received in PPD Central lab. Please reconcile the correct date and update if applicable. Else clarify.' answered with 'Please note that a DCF has been submitted.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	11 Nov 2020 15:14:30
User opened query 'Per GCL Lab Reconciliation: Sample dated 09Oct2020 is recorded under Visit2 Day29 visit in EDC, however a sample dated 08Oct2020 was received in PPD Central lab. Please reconcile the correct date and update if applicable. Else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:45:41
User entered '9 Oct 2020'		09 Oct 2020 21:35:48

US3322314

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:23:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11:10'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:35:48

US3322314

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '09 Oct 2020 11:10'	System	11 Nov 2020 15:14:36
User entered '9 Oct 2020 11:10'	System	09 Oct 2020 21:35:48

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:08:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-OCT-2020 is reported under Unscheduled visit in PPD portal; however, swab sample is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate and clarify the correct visit name for swab sample collected on 08-OCT-2020.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 07:48:35
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-OCT-2020 is reported under Unscheduled visit in PPD portal; however, swab sample is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate and clarify the correct visit name for swab sample collected on 08-OCT-2020.' answered with 'sample was taken during V2, which was on 9-Oct-2020. There are no samples dated 8-Oct-2020 in source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	14 Dec 2020 14:29:32
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-OCT-2020 is reported under Unscheduled visit in PPD portal; however, swab sample is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate and clarify the correct visit name for swab sample collected on 08-OCT-2020.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 05:03:08
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 09-OCT-2020 is recorded under Visit 2 Day 29 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).		04 Dec 2020 09:01:04

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:08:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 09-OCT-2020 is recorded under Visit 2 Day 29 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 11:25:39
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "09-OCT-2020" is recorded under Visit 2 Day 29 in EDC; however, in PPD Central lab, it is recorded as "08-OCT-2020" for Visit 2 Day 29. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).		24 Nov 2020 10:32:33
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "09-OCT-2020" is recorded under Visit 2 Day 29 in EDC; however, in PPD Central lab, it is recorded as "08-OCT-2020" for Visit 2 Day 29. Kindly review the collection date and update as appropriate, else clarify.' answered with 'DCF has been submitted. Sample was collected on 09-Oct-2020.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	12 Nov 2020 19:26:50
User entered '09 Oct 2020' reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	12 Nov 2020 19:23:16
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "09-OCT-2020" is recorded under Visit 2 Day 29 in EDC; however, in PPD Central lab, it is recorded as "08-OCT-2020" for Visit 2 Day 29. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 06:20:20
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 21:36:20

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		09 Oct 2020 21:36:20

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:36:20

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '11:05'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:36:20

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '09 Oct 2020 11:05'	System	12 Nov 2020 19:23:16
User entered '9 Oct 2020 11:05'	System	09 Oct 2020 21:36:20

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		09 Oct 2020 21:36:20

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:36:20

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:23:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:36:20

US3322314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered empty.	System	09 Oct 2020 21:36:20

US3322314

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:23:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:36:25

US3322314

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'I'	System	09 Oct 2020 21:36:25

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:13', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8fb301b4-37a1-4069-b839-b05017bbe2e4'	System	09 Oct 2020 16:57:33
User entered 'Yes (Y)'	System	09 Oct 2020 16:57:33

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:18', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8fb301b4-37a1-4069-b839-b05017bbe2e4'	System	09 Oct 2020 16:57:33
User entered '98.2'	System	09 Oct 2020 16:57:33

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:22', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8fb301b4-37a1-4069-b839-b05017bbe2e4'	System	09 Oct 2020 16:57:33
User entered 'No (N)'	System	09 Oct 2020 16:57:33

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:28', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8fb301b4-37a1-4069-b839-b05017bbe2e4'	System	09 Oct 2020 16:57:33
User entered '09 Oct 2020 11:57'	System	09 Oct 2020 16:57:33

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '09 Oct 2020 11:45'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '09 Oct 2020 14:15'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:20:30', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '64529bb1-39ec-4494-a4ed-6639dc6b15e2'	System	09 Oct 2020 21:20:44
User entered 'Yes (Y)'	System	09 Oct 2020 21:20:44

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:20:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '64529bb1-39ec-4494-a4ed-6639dc6b15e2'	System	09 Oct 2020 21:20:44
User entered '98.2'	System	09 Oct 2020 21:20:44

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:20:37', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '64529bb1-39ec-4494-a4ed-6639dc6b15e2'	System	09 Oct 2020 21:20:44
User entered 'No (N)'	System	09 Oct 2020 21:20:44

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:20:40', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '64529bb1-39ec-4494-a4ed-6639dc6b15e2'	System	09 Oct 2020 21:20:44
User entered '09 Oct 2020 16:20'	System	09 Oct 2020 21:20:44

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '09 Oct 2020 15:10'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 2'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:11:17', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd9685505-97d0-437a-8a54-c368740d5f02'	System	10 Oct 2020 20:11:34
User entered 'Yes (Y)'	System	10 Oct 2020 20:11:34

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:11:21', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd9685505-97d0-437a-8a54-c368740d5f02'	System	10 Oct 2020 20:11:34
User entered '98.0'	System	10 Oct 2020 20:11:34

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:11:25', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd9685505-97d0-437a-8a54-c368740d5f02'	System	10 Oct 2020 20:11:34
User entered 'No (N)'	System	10 Oct 2020 20:11:34

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:11:31', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd9685505-97d0-437a-8a54-c368740d5f02'	System	10 Oct 2020 20:11:34
User entered '10 Oct 2020 15:11'	System	10 Oct 2020 20:11:34

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 3'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:13:38', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'f411f8cc-08e4-4a57-ac20-b5083527048d'	System	11 Oct 2020 20:13:53
User entered 'Yes (Y)'	System	11 Oct 2020 20:13:53

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:13:42', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'f411f8cc-08e4-4a57-ac20-b5083527048d' User entered '98.0'	System	11 Oct 2020 20:13:53
	System	11 Oct 2020 20:13:53

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:13:46', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'f411f8cc-08e4-4a57-ac20-b5083527048d'	System	11 Oct 2020 20:13:53
User entered 'No (N)'	System	11 Oct 2020 20:13:53

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:13:49', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'f411f8cc-08e4-4a57-ac20-b5083527048d'	System	11 Oct 2020 20:13:53
User entered '11 Oct 2020 15:13'	System	11 Oct 2020 20:13:53

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 4'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:51:11', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8b081b5f-d520-4272-ac5c-c5ee987ab31f'	System	13 Oct 2020 09:51:24
User entered 'Yes (Y)'	System	13 Oct 2020 09:51:24

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:51:16', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8b081b5f-d520-4272-ac5c-c5ee987ab31f' User entered '98.0'	System	13 Oct 2020 09:51:24
	System	13 Oct 2020 09:51:24

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:51:19', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8b081b5f-d520-4272-ac5c-c5ee987ab31f'	System	13 Oct 2020 09:51:24
User entered 'No (N)'	System	13 Oct 2020 09:51:24

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:51:22', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8b081b5f-d520-4272-ac5c-c5ee987ab31f' User entered '13 Oct 2020 04:51'	System	13 Oct 2020 09:51:24
	System	13 Oct 2020 09:51:24

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 5'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:27:44', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '805a5847-5862-4d03-bce1-0a7459bce9d6'	System	14 Oct 2020 01:28:08
User entered 'Yes (Y)'	System	14 Oct 2020 01:28:08

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:27:49', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '805a5847-5862-4d03-bce1-0a7459bce9d6' User entered '98.3'	System	14 Oct 2020 01:28:08
	System	14 Oct 2020 01:28:08

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:27:52', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '805a5847-5862-4d03-bce1-0a7459bce9d6'	System	14 Oct 2020 01:28:08
User entered 'No (N)'	System	14 Oct 2020 01:28:08

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:04', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '805a5847-5862-4d03-bce1-0a7459bce9d6'	System	14 Oct 2020 01:28:08
User entered '13 Oct 2020 20:28'	System	14 Oct 2020 01:28:08

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 6'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:43:51', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '205d88b4-0432-494b-9bd1-bef0173dab81'	System	14 Oct 2020 22:44:09
User entered 'Yes (Y)'	System	14 Oct 2020 22:44:09

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:43:55', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '205d88b4-0432-494b-9bd1-bef0173dab81'	System	14 Oct 2020 22:44:09
User entered '98.3'	System	14 Oct 2020 22:44:09

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:43:59', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '205d88b4-0432-494b-9bd1-bef0173dab81'	System	14 Oct 2020 22:44:09
User entered 'No (N)'	System	14 Oct 2020 22:44:09

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:05', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '205d88b4-0432-494b-9bd1-bef0173dab81'	System	14 Oct 2020 22:44:09
User entered '14 Oct 2020 17:44'	System	14 Oct 2020 22:44:09

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 7'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:38:58', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cf1730cd-0e3f-4027-ab3e-c59ed2811e10'	System	16 Oct 2020 00:39:13
User entered 'Yes (Y)'	System	16 Oct 2020 00:39:13

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:02', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cf1730cd-0e3f-4027-ab3e-c59ed2811e10'	System	16 Oct 2020 00:39:13
User entered '98.0'	System	16 Oct 2020 00:39:13

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:06', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cf1730cd-0e3f-4027-ab3e-c59ed2811e10'	System	16 Oct 2020 00:39:13
User entered 'No (N)'	System	16 Oct 2020 00:39:13

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:09', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cf1730cd-0e3f-4027-ab3e-c59ed2811e10'	System	16 Oct 2020 00:39:13
User entered '15 Oct 2020 19:39'	System	16 Oct 2020 00:39:13

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b10ff19e-a24b-4bc2-b2fc-40eeab9e9c17'	System	09 Oct 2020 16:57:55
User entered 'None (1)'	System	09 Oct 2020 16:57:55

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:40', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b10ff19e-a24b-4bc2-b2fc-40eeab9e9c17'	System	09 Oct 2020 16:57:55
User entered 'No (N)'	System	09 Oct 2020 16:57:55

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:45', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b10ff19e-a24b-4bc2-b2fc-40eeab9e9c17'	System	09 Oct 2020 16:57:55
User entered 'No (N)'	System	09 Oct 2020 16:57:55

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:49', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b10ff19e-a24b-4bc2-b2fc-40eeab9e9c17'	System	09 Oct 2020 16:57:55
User entered 'None (1)'	System	09 Oct 2020 16:57:55

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:51', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b10ff19e-a24b-4bc2-b2fc-40eeab9e9c17'	System	09 Oct 2020 16:57:55
User entered '09 Oct 2020 11:57'	System	09 Oct 2020 16:57:55

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '09 Oct 2020 11:45'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '09 Oct 2020 14:15'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:20:47', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e04f7db0-7f98-4851-86a7-1af0a1ae22a3'	System	09 Oct 2020 21:21:08
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 21:21:08

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:20:51', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e04f7db0-7f98-4851-86a7-1af0a1ae22a3'	System	09 Oct 2020 21:21:08
User entered 'No (N)'	System	09 Oct 2020 21:21:08

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:20:54', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e04f7db0-7f98-4851-86a7-1af0a1ae22a3'	System	09 Oct 2020 21:21:08
User entered 'No (N)'	System	09 Oct 2020 21:21:08

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:21:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e04f7db0-7f98-4851-86a7-1af0a1ae22a3'	System	09 Oct 2020 21:21:08
User entered 'None (1)'	System	09 Oct 2020 21:21:08

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:21:05', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e04f7db0-7f98-4851-86a7-1af0a1ae22a3'	System	09 Oct 2020 21:21:08
User entered '09 Oct 2020 16:21'	System	09 Oct 2020 21:21:08

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '09 Oct 2020 15:10'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 2'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:11:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'fac0bad1-3d85-4f60-a47e-7a4311db993a'	System	10 Oct 2020 20:11:58
User entered 'Does not interfere with activity (2)'	System	10 Oct 2020 20:11:58

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:11:44', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'fac0bad1-3d85-4f60-a47e-7a4311db993a'	System	10 Oct 2020 20:11:58
User entered 'No (N)'	System	10 Oct 2020 20:11:58

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:11:47', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'fac0bad1-3d85-4f60-a47e-7a4311db993a'	System	10 Oct 2020 20:11:58
User entered 'No (N)'	System	10 Oct 2020 20:11:58

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:11:53', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'fac0bad1-3d85-4f60-a47e-7a4311db993a'	System	10 Oct 2020 20:11:58
User entered 'None (1)'	System	10 Oct 2020 20:11:58

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:11:55', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'fac0bad1-3d85-4f60-a47e-7a4311db993a'	System	10 Oct 2020 20:11:58
User entered '10 Oct 2020 15:11'	System	10 Oct 2020 20:11:58

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 3'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:13:53', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '63a12f91-f730-4694-89a4-1f3110ed6bfe'	System	11 Oct 2020 20:14:07
User entered 'None (1)'	System	11 Oct 2020 20:14:07

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:13:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '63a12f91-f730-4694-89a4-1f3110ed6bfe'	System	11 Oct 2020 20:14:07
User entered 'No (N)'	System	11 Oct 2020 20:14:07

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:13:59', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '63a12f91-f730-4694-89a4-1f3110ed6bfe'	System	11 Oct 2020 20:14:07
User entered 'No (N)'	System	11 Oct 2020 20:14:07

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:14:02', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '63a12f91-f730-4694-89a4-1f3110ed6bfe'	System	11 Oct 2020 20:14:07
User entered 'None (1)'	System	11 Oct 2020 20:14:07

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:14:04', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '63a12f91-f730-4694-89a4-1f3110ed6bfe' User entered '11 Oct 2020 15:14'	System	11 Oct 2020 20:14:07
	System	11 Oct 2020 20:14:07

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 4'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:51:36', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a55a901a-7ffd-4651-882d-1edde39bf86f'	System	13 Oct 2020 09:51:50
User entered 'None (1)'	System	13 Oct 2020 09:51:50

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:51:39', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a55a901a-7ffd-4651-882d-1edde39bf86f'	System	13 Oct 2020 09:51:50
User entered 'No (N)'	System	13 Oct 2020 09:51:50

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:51:42', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a55a901a-7ffd-4651-882d-1edde39bf86f'	System	13 Oct 2020 09:51:50
User entered 'No (N)'	System	13 Oct 2020 09:51:50

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:51:44', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a55a901a-7ffd-4651-882d-1edde39bf86f'	System	13 Oct 2020 09:51:50
User entered 'None (1)'	System	13 Oct 2020 09:51:50

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:51:47', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a55a901a-7ffd-4651-882d-1edde39bf86f' User entered '13 Oct 2020 04:51'	System	13 Oct 2020 09:51:50
	System	13 Oct 2020 09:51:50

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 5'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:08', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '32e77cf1-30e0-42ad-907a-582c0bf9570a'	System	14 Oct 2020 01:28:36
User entered 'None (1)'	System	14 Oct 2020 01:28:36

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:21', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '32e77cf1-30e0-42ad-907a-582c0bf9570a'	System	14 Oct 2020 01:28:36
User entered 'No (N)'	System	14 Oct 2020 01:28:36

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:24', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '32e77cf1-30e0-42ad-907a-582c0bf9570a'	System	14 Oct 2020 01:28:36
User entered 'No (N)'	System	14 Oct 2020 01:28:36

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:26', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '32e77cf1-30e0-42ad-907a-582c0bf9570a'	System	14 Oct 2020 01:28:36
User entered 'None (1)'	System	14 Oct 2020 01:28:36

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:30', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '32e77cf1-30e0-42ad-907a-582c0bf9570a'	System	14 Oct 2020 01:28:36
User entered '13 Oct 2020 20:28'	System	14 Oct 2020 01:28:36

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 6'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:08', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'ad2fe1eb-df1c-4674-83c8-682bdfa2d2d2'	System	14 Oct 2020 22:44:25
User entered 'None (1)'	System	14 Oct 2020 22:44:25

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:11', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'ad2fe1eb-df1c-4674-83c8-682bdfa2d2d2'	System	14 Oct 2020 22:44:25
User entered 'No (N)'	System	14 Oct 2020 22:44:25

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:13', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'ad2fe1eb-df1c-4674-83c8-682bdfa2d2d2'	System	14 Oct 2020 22:44:25
User entered 'No (N)'	System	14 Oct 2020 22:44:25

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:17', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'ad2fe1eb-df1c-4674-83c8-682bdfa2d2d2'	System	14 Oct 2020 22:44:25
User entered 'None (1)'	System	14 Oct 2020 22:44:25

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:19', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'ad2fe1eb-df1c-4674-83c8-682bdfa2d2d2'	System	14 Oct 2020 22:44:25
User entered '14 Oct 2020 17:44'	System	14 Oct 2020 22:44:25

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 7'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:12', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '2e82ca2c-c074-44d8-8b22-7603c14d941a'	System	16 Oct 2020 00:39:27
User entered 'None (1)'	System	16 Oct 2020 00:39:27

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:15', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '2e82ca2c-c074-44d8-8b22-7603c14d941a'	System	16 Oct 2020 00:39:27
User entered 'No (N)'	System	16 Oct 2020 00:39:27

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:18', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '2e82ca2c-c074-44d8-8b22-7603c14d941a'	System	16 Oct 2020 00:39:27
User entered 'No (N)'	System	16 Oct 2020 00:39:27

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:20', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '2e82ca2c-c074-44d8-8b22-7603c14d941a'	System	16 Oct 2020 00:39:27
User entered 'None (1)'	System	16 Oct 2020 00:39:27

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:23', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '2e82ca2c-c074-44d8-8b22-7603c14d941a'	System	16 Oct 2020 00:39:27
User entered '15 Oct 2020 19:39'	System	16 Oct 2020 00:39:27

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e21bc9eb-4d79-450d-bb50-0769f1a9737e'	System	09 Oct 2020 16:59:00
User entered 'None (0)'	System	09 Oct 2020 16:59:00

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:57:59', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e21bc9eb-4d79-450d-bb50-0769f1a9737e'	System	09 Oct 2020 16:59:00
User entered 'None (0)'	System	09 Oct 2020 16:59:00

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:58:37', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e21bc9eb-4d79-450d-bb50-0769f1a9737e'	System	09 Oct 2020 16:59:00
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:59:00

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:58:40', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e21bc9eb-4d79-450d-bb50-0769f1a9737e'	System	09 Oct 2020 16:59:00
User entered 'No interference with activity (1)'	System	09 Oct 2020 16:59:00

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:58:44', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e21bc9eb-4d79-450d-bb50-0769f1a9737e'	System	09 Oct 2020 16:59:00
User entered 'None (0)'	System	09 Oct 2020 16:59:00

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:58:47', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e21bc9eb-4d79-450d-bb50-0769f1a9737e'	System	09 Oct 2020 16:59:00
User entered 'None (0)'	System	09 Oct 2020 16:59:00

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:58:53', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e21bc9eb-4d79-450d-bb50-0769f1a9737e'	System	09 Oct 2020 16:59:00
User entered 'No (N)'	System	09 Oct 2020 16:59:00

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T11:58:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e21bc9eb-4d79-450d-bb50-0769f1a9737e' User entered '09 Oct 2020 11:58'	System	09 Oct 2020 16:59:00
	System	09 Oct 2020 16:59:00

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '09 Oct 2020 11:45'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '09 Oct 2020 14:15'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:21:09', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd6de31fb-4309-4fc9-a8cf-8f3bf4aa8f7d'	System	09 Oct 2020 21:21:47
User entered 'None (0)'	System	09 Oct 2020 21:21:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:21:15', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd6de31fb-4309-4fc9-a8cf-8f3bf4aa8f7d'	System	09 Oct 2020 21:21:47
User entered 'None (0)'	System	09 Oct 2020 21:21:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:21:19', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd6de31fb-4309-4fc9-a8cf-8f3bf4aa8f7d'	System	09 Oct 2020 21:21:47
User entered 'None (0)'	System	09 Oct 2020 21:21:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:21:25', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd6de31fb-4309-4fc9-a8cf-8f3bf4aa8f7d'	System	09 Oct 2020 21:21:47
User entered 'None (0)'	System	09 Oct 2020 21:21:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:21:29', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd6de31fb-4309-4fc9-a8cf-8f3bf4aa8f7d'	System	09 Oct 2020 21:21:47
User entered 'None (0)'	System	09 Oct 2020 21:21:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:21:32', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd6de31fb-4309-4fc9-a8cf-8f3bf4aa8f7d'	System	09 Oct 2020 21:21:47
User entered 'None (0)'	System	09 Oct 2020 21:21:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:21:38', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd6de31fb-4309-4fc9-a8cf-8f3bf4aa8f7d'	System	09 Oct 2020 21:21:47
User entered 'No (N)'	System	09 Oct 2020 21:21:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-09T16:21:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'd6de31fb-4309-4fc9-a8cf-8f3bf4aa8f7d'	System	09 Oct 2020 21:21:47
User entered '09 Oct 2020 16:21'	System	09 Oct 2020 21:21:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '09 Oct 2020 15:10'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 2'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:12:03', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2d85140-a4f8-4e38-8bab-b89b663be6ef'	System	10 Oct 2020 20:12:40
User entered 'No interference with activity (1)'	System	10 Oct 2020 20:12:40

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:12:10', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2d85140-a4f8-4e38-8bab-b89b663be6ef'	System	10 Oct 2020 20:12:40
User entered 'Some interference with activity (2)'	System	10 Oct 2020 20:12:40

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:12:17', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2d85140-a4f8-4e38-8bab-b89b663be6ef'	System	10 Oct 2020 20:12:40
User entered 'None (0)'	System	10 Oct 2020 20:12:40

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:12:21', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2d85140-a4f8-4e38-8bab-b89b663be6ef'	System	10 Oct 2020 20:12:40
User entered 'None (0)'	System	10 Oct 2020 20:12:40

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:12:25', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2d85140-a4f8-4e38-8bab-b89b663be6ef'	System	10 Oct 2020 20:12:40
User entered 'None (0)'	System	10 Oct 2020 20:12:40

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:12:28', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2d85140-a4f8-4e38-8bab-b89b663be6ef'	System	10 Oct 2020 20:12:40
User entered 'None (0)'	System	10 Oct 2020 20:12:40

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:12:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2d85140-a4f8-4e38-8bab-b89b663be6ef'	System	10 Oct 2020 20:12:40
User entered 'No (N)'	System	10 Oct 2020 20:12:40

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-10T15:12:36', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b2d85140-a4f8-4e38-8bab-b89b663be6ef'	System	10 Oct 2020 20:12:40
User entered '10 Oct 2020 15:12'	System	10 Oct 2020 20:12:40

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 3'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:14:09', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e7602ee5-3cdc-46d5-bb88-f19a6673527d' User entered 'None (0)'	System	11 Oct 2020 20:14:29
	System	11 Oct 2020 20:14:29

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:14:13', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e7602ee5-3cdc-46d5-bb88-f19a6673527d' User entered 'None (0)'	System	11 Oct 2020 20:14:29
	System	11 Oct 2020 20:14:29

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:14:15', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e7602ee5-3cdc-46d5-bb88-f19a6673527d' User entered 'None (0)'	System	11 Oct 2020 20:14:29
	System	11 Oct 2020 20:14:29

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:14:17', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e7602ee5-3cdc-46d5-bb88-f19a6673527d' User entered 'None (0)'	System	11 Oct 2020 20:14:29
	System	11 Oct 2020 20:14:29

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:14:19', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e7602ee5-3cdc-46d5-bb88-f19a6673527d' User entered 'None (0)'	System	11 Oct 2020 20:14:29
	System	11 Oct 2020 20:14:29

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:14:21', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e7602ee5-3cdc-46d5-bb88-f19a6673527d'	System	11 Oct 2020 20:14:29
User entered 'None (0)'	System	11 Oct 2020 20:14:29

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:14:24', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e7602ee5-3cdc-46d5-bb88-f19a6673527d'	System	11 Oct 2020 20:14:29
User entered 'No (N)'	System	11 Oct 2020 20:14:29

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-11T15:14:27', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'e7602ee5-3cdc-46d5-bb88-f19a6673527d'	System	11 Oct 2020 20:14:29
User entered '11 Oct 2020 15:14'	System	11 Oct 2020 20:14:29

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 4'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:51:57', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9af4603c-e2f3-401c-9080-50c80413d69e'	System	13 Oct 2020 09:52:31
User entered 'None (0)'	System	13 Oct 2020 09:52:31

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:52:05', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9af4603c-e2f3-401c-9080-50c80413d69e'	System	13 Oct 2020 09:52:31
User entered 'None (0)'	System	13 Oct 2020 09:52:31

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:52:13', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9af4603c-e2f3-401c-9080-50c80413d69e'	System	13 Oct 2020 09:52:31
User entered 'None (0)'	System	13 Oct 2020 09:52:31

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:52:19', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9af4603c-e2f3-401c-9080-50c80413d69e'	System	13 Oct 2020 09:52:31
User entered 'None (0)'	System	13 Oct 2020 09:52:31

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:52:22', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9af4603c-e2f3-401c-9080-50c80413d69e'	System	13 Oct 2020 09:52:31
User entered 'None (0)'	System	13 Oct 2020 09:52:31

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:52:24', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9af4603c-e2f3-401c-9080-50c80413d69e'	System	13 Oct 2020 09:52:31
User entered 'None (0)'	System	13 Oct 2020 09:52:31

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:52:27', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9af4603c-e2f3-401c-9080-50c80413d69e'	System	13 Oct 2020 09:52:31
User entered 'No (N)'	System	13 Oct 2020 09:52:31

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T04:52:30', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9af4603c-e2f3-401c-9080-50c80413d69e'	System	13 Oct 2020 09:52:31
User entered '13 Oct 2020 04:52'	System	13 Oct 2020 09:52:31

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 5'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '1ffce555-ce1f-4a10-8413-fb49e2be9357'	System	14 Oct 2020 01:28:57
User entered 'None (0)'	System	14 Oct 2020 01:28:57

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:37', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '1ffce555-ce1f-4a10-8413-fb49e2be9357'	System	14 Oct 2020 01:28:57
User entered 'None (0)'	System	14 Oct 2020 01:28:57

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:39', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '1ffce555-ce1f-4a10-8413-fb49e2be9357'	System	14 Oct 2020 01:28:57
User entered 'None (0)'	System	14 Oct 2020 01:28:57

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '1ffce555-ce1f-4a10-8413-fb49e2be9357'	System	14 Oct 2020 01:28:57
User entered 'None (0)'	System	14 Oct 2020 01:28:57

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:43', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '1ffce555-ce1f-4a10-8413-fb49e2be9357'	System	14 Oct 2020 01:28:57
User entered 'None (0)'	System	14 Oct 2020 01:28:57

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:45', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '1ffce555-ce1f-4a10-8413-fb49e2be9357'	System	14 Oct 2020 01:28:57
User entered 'None (0)'	System	14 Oct 2020 01:28:57

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:49', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '1ffce555-ce1f-4a10-8413-fb49e2be9357'	System	14 Oct 2020 01:28:57
User entered 'No (N)'	System	14 Oct 2020 01:28:57

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-13T20:28:53', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '1ffce555-ce1f-4a10-8413-fb49e2be9357'	System	14 Oct 2020 01:28:57
User entered '13 Oct 2020 20:28'	System	14 Oct 2020 01:28:57

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 6'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:26', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23bcd799-2eac-41d3-9500-691eff8e8ba4'	System	14 Oct 2020 22:44:43
User entered 'None (0)'	System	14 Oct 2020 22:44:43

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:28', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23bcd799-2eac-41d3-9500-691eff8e8ba4'	System	14 Oct 2020 22:44:43
User entered 'None (0)'	System	14 Oct 2020 22:44:43

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:30', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23bcd799-2eac-41d3-9500-691eff8e8ba4'	System	14 Oct 2020 22:44:43
User entered 'None (0)'	System	14 Oct 2020 22:44:43

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:32', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23bcd799-2eac-41d3-9500-691eff8e8ba4'	System	14 Oct 2020 22:44:43
User entered 'None (0)'	System	14 Oct 2020 22:44:43

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23bcd799-2eac-41d3-9500-691eff8e8ba4'	System	14 Oct 2020 22:44:43
User entered 'None (0)'	System	14 Oct 2020 22:44:43

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:36', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23bcd799-2eac-41d3-9500-691eff8e8ba4'	System	14 Oct 2020 22:44:43
User entered 'None (0)'	System	14 Oct 2020 22:44:43

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:38', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23bcd799-2eac-41d3-9500-691eff8e8ba4'	System	14 Oct 2020 22:44:43
User entered 'No (N)'	System	14 Oct 2020 22:44:43

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-14T17:44:40', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23bcd799-2eac-41d3-9500-691eff8e8ba4'	System	14 Oct 2020 22:44:43
User entered '14 Oct 2020 17:44'	System	14 Oct 2020 22:44:43

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	09 Oct 2020 16:33:21
User entered 'Day 7'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:28', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc4fd18e-3403-44ee-bc91-4799e225f831'	System	16 Oct 2020 00:39:47
User entered 'None (0)'	System	16 Oct 2020 00:39:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:30', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc4fd18e-3403-44ee-bc91-4799e225f831'	System	16 Oct 2020 00:39:47
User entered 'None (0)'	System	16 Oct 2020 00:39:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:32', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc4fd18e-3403-44ee-bc91-4799e225f831'	System	16 Oct 2020 00:39:47
User entered 'None (0)'	System	16 Oct 2020 00:39:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc4fd18e-3403-44ee-bc91-4799e225f831'	System	16 Oct 2020 00:39:47
User entered 'None (0)'	System	16 Oct 2020 00:39:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:36', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc4fd18e-3403-44ee-bc91-4799e225f831'	System	16 Oct 2020 00:39:47
User entered 'None (0)'	System	16 Oct 2020 00:39:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:38', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc4fd18e-3403-44ee-bc91-4799e225f831'	System	16 Oct 2020 00:39:47
User entered 'None (0)'	System	16 Oct 2020 00:39:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:40', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc4fd18e-3403-44ee-bc91-4799e225f831'	System	16 Oct 2020 00:39:47
User entered 'No (N)'	System	16 Oct 2020 00:39:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-10-15T19:39:44', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc4fd18e-3403-44ee-bc91-4799e225f831'	System	16 Oct 2020 00:39:47
User entered '15 Oct 2020 19:39'	System	16 Oct 2020 00:39:47

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 16:33:21

US3322314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 16:33:21

US3322314

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:25:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 14:40:54

US3322314

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:25:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '16 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 14:40:54

US3322314

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:25:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 14:40:54

US3322314

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:25:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 14:40:54

US3322314

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:25:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 14:40:59

US3322314

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'I'	System	19 Oct 2020 14:40:59

US3322314

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:26:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 19:19:50

US3322314

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:26:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '23 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 19:19:50

US3322314

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:26:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 19:19:50

US3322314

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:26:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 19:19:50

US3322314

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:26:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 19:19:55

US3322314

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'I'	System	23 Oct 2020 19:19:55

US3322314

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:27:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 19:31:04

US3322314

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:27:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '2 Nov 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 19:31:04

US3322314

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:27:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 19:31:04

US3322314

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:27:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 19:31:04

US3322314

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:27:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 19:30:54

US3322314

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'I'	System	02 Nov 2020 19:30:54

US3322314

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:10:56

US3322314

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '3 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:10:56

US3322314

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Clinic (Clinic)'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:10:56

US3322314

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'VISIT3'	System	03 Nov 2020 16:10:56

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '3 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '09:32'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '3 Nov 2020 09:32'	System	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '97.2' F	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Oral (Oral)'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4)	
	Moez Talpur (b) (4)	03 Nov 2020 16:11:42
	(b) (4)	

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '73'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'bpm'	System	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '16'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'breaths/min'	System	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '116'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'mmHg'	System	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:28:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '70'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'mmHg'	System	03 Nov 2020 16:11:42

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02

US3322314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02

US3322314

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:29:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:50

US3322314

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:29:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '3 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:11:50

US3322314

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:29:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:12:07

US3322314

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:29:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '3 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:12:07

US3322314

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:29:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '09:31' reason for change: Data Entry Error	(b) (4)	
	Moez Talpur (b) (4)	03 Nov 2020 16:12:19
User entered '09:32'	(b) (4)	
	Moez Talpur (b) (4)	03 Nov 2020 16:12:07
	(b) (4)	

US3322314

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered '3 Nov 2020 09:31'	System	03 Nov 2020 16:12:19
User entered '3 Nov 2020 09:32'	System	03 Nov 2020 16:12:07

US3322314

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:29:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	03 Nov 2020 16:12:31

US3322314

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'I'	System	03 Nov 2020 16:12:31

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 64'	System	11 Sep 2020 16:00:21

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-11-11T14:28:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '3172d243-1526-4a97-9fc1-5266f26245bc'	System	11 Nov 2020 20:28:47
User entered 'No (N)'	System	11 Nov 2020 20:28:47

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-11-11T14:28:38', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '3172d243-1526-4a97-9fc1-5266f26245bc'	System	11 Nov 2020 20:28:47
User entered 'No (N)'	System	11 Nov 2020 20:28:47

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-11-11T14:28:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '3172d243-1526-4a97-9fc1-5266f26245bc'	System	11 Nov 2020 20:28:47
User entered '11 Nov 2020 14:28:41'	System	11 Nov 2020 20:28:47

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 16:00:21

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered 'Day 71'	System	11 Sep 2020 16:00:21

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-11-18T03:46:27', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '935df6ea-edd4-47d5-9230-37b82a933296'	System	18 Nov 2020 09:46:46
User entered 'No (N)'	System	18 Nov 2020 09:46:46

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-11-18T03:46:35', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '935df6ea-edd4-47d5-9230-37b82a933296'	System	18 Nov 2020 09:46:46
User entered 'No (N)'	System	18 Nov 2020 09:46:46

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-11-18T03:46:39', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '935df6ea-edd4-47d5-9230-37b82a933296'	System	18 Nov 2020 09:46:46
User entered '18 Nov 2020 03:46:39'	System	18 Nov 2020 09:46:46

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 16:00:21

US3322314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:53:05
Data entry locked.	System	11 Sep 2020 16:00:21
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 16:00:21

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2020-11-22T07:35:03', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b6a9cac0-1f73-4cd3-b340-fd209050456b'	System	22 Nov 2020 13:35:22
User entered 'No (N)'	System	22 Nov 2020 13:35:22

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2020-11-22T07:35:13', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b6a9cac0-1f73-4cd3-b340-fd209050456b'	System	22 Nov 2020 13:35:22
User entered 'No (N)'	System	22 Nov 2020 13:35:22

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-11-22T07:35:16', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b6a9cac0-1f73-4cd3-b340-fd209050456b'	System	22 Nov 2020 13:35:22
User entered '22 Nov 2020 07:35:16'	System	22 Nov 2020 13:35:22

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2020-11-29T07:42:31', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6bba1dd4-c255-468b-b893-98a456fbd423'	System	29 Nov 2020 13:42:40
User entered 'No (N)'	System	29 Nov 2020 13:42:40

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2020-11-29T07:42:35', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6bba1dd4-c255-468b-b893-98a456fbd423'	System	29 Nov 2020 13:42:40
User entered 'No (N)'	System	29 Nov 2020 13:42:40

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-11-29T07:42:38', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6bba1dd4-c255-468b-b893-98a456fbd423'	System	29 Nov 2020 13:42:40
User entered '29 Nov 2020 07:42:38'	System	29 Nov 2020 13:42:40

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2020-12-06T19:16:54', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered 'Yes (Y)'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:02', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered 'Yes (Y)'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Please 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 (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:11', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:17', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered 'Yes (Y)'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '1'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '0'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '1'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f' User entered '0'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '0'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '1'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '1'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '1'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '1'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '0'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '0'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '1'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '0'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '1'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '0'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '0'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered '0'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Please 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 (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:37', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f'	System	07 Dec 2020 01:17:56
User entered 'No (N)'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-06T19:17:47', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'cc89ffd4-c693-48e4-a4cd-40a25473eb3f' User entered '06 Dec 2020 19:17:47'	System	07 Dec 2020 01:17:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2020-12-13T05:26:05', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '024e154f-688d-45d9-b48b-c789defb8958'	System	13 Dec 2020 11:26:43
User entered 'Yes (Y)'	System	13 Dec 2020 11:26:43

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2020-12-13T05:26:15', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '024e154f-688d-45d9-b48b-c789defb8958'	System	13 Dec 2020 11:26:43
User entered 'No (N)'	System	13 Dec 2020 11:26:43

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-13T05:26:21', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '024e154f-688d-45d9-b48b-c789defb8958'	System	13 Dec 2020 11:26:43
User entered 'No (N)'	System	13 Dec 2020 11:26:43

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-13T05:26:36', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '024e154f-688d-45d9-b48b-c789defb8958'	System	13 Dec 2020 11:26:43
User entered 'No (N)'	System	13 Dec 2020 11:26:43

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-13T05:26:40', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '024e154f-688d-45d9-b48b-c789defb8958'	System	13 Dec 2020 11:26:43
User entered '13 Dec 2020 05:26:40'	System	13 Dec 2020 11:26:43

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2020-12-20T07:40:09', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'aa41272b-b60e-494c-bd5b-699c5813463a'	System	20 Dec 2020 13:40:20
User entered 'No (N)'	System	20 Dec 2020 13:40:20

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2020-12-20T07:40:13', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'aa41272b-b60e-494c-bd5b-699c5813463a'	System	20 Dec 2020 13:40:20
User entered 'No (N)'	System	20 Dec 2020 13:40:20

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-20T07:40:15', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'aa41272b-b60e-494c-bd5b-699c5813463a'	System	20 Dec 2020 13:40:20
User entered '20 Dec 2020 07:40:15'	System	20 Dec 2020 13:40:20

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2020-12-27T07:13:21', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '60de64e2-0c39-40d2-9636-22fd981c9e94'	System	27 Dec 2020 13:13:51
User entered 'No (N)'	System	27 Dec 2020 13:13:51

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2020-12-27T07:13:26', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '60de64e2-0c39-40d2-9636-22fd981c9e94'	System	27 Dec 2020 13:13:51
User entered 'Yes (Y)'	System	27 Dec 2020 13:13:51

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Please 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 (ba59af6f7bf7e24d)', Time: '2020-12-27T07:13:36', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '60de64e2-0c39-40d2-9636-22fd981c9e94'	System	27 Dec 2020 13:13:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 13:13:51

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2020-12-27T07:13:42', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '60de64e2-0c39-40d2-9636-22fd981c9e94'	System	27 Dec 2020 13:13:51
User entered '27 Dec 2020 07:13:42'	System	27 Dec 2020 13:13:51

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-01-03T07:57:21', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'f3015302-27a3-4bec-92c6-6583a4f40d3b'	System	03 Jan 2021 13:57:31
User entered 'No (N)'	System	03 Jan 2021 13:57:31

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-01-03T07:57:25', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'f3015302-27a3-4bec-92c6-6583a4f40d3b'	System	03 Jan 2021 13:57:31
User entered 'No (N)'	System	03 Jan 2021 13:57:31

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-01-03T07:57:28', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'f3015302-27a3-4bec-92c6-6583a4f40d3b'	System	03 Jan 2021 13:57:31
User entered '03 Jan 2021 07:57:28'	System	03 Jan 2021 13:57:31

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-01-11T05:19:34', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'adc55eae-ea95-45e0-afbb-d5f1d081df96'	System	11 Jan 2021 11:19:42
User entered 'No (N)'	System	11 Jan 2021 11:19:42

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-01-11T05:19:38', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'adc55eae-ea95-45e0-afbb-d5f1d081df96'	System	11 Jan 2021 11:19:42
User entered 'No (N)'	System	11 Jan 2021 11:19:42

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-01-11T05:19:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'adc55eae-ea95-45e0-afbb-d5f1d081df96'	System	11 Jan 2021 11:19:42
User entered '11 Jan 2021 05:19:41'	System	11 Jan 2021 11:19:42

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-01-17T07:57:28', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b0e7dead-a0d5-40f9-b505-57522e0025e8'	System	17 Jan 2021 13:57:37
User entered 'No (N)'	System	17 Jan 2021 13:57:37

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-01-17T07:57:31', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b0e7dead-a0d5-40f9-b505-57522e0025e8'	System	17 Jan 2021 13:57:37
User entered 'No (N)'	System	17 Jan 2021 13:57:37

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-01-17T07:57:33', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b0e7dead-a0d5-40f9-b505-57522e0025e8' User entered '17 Jan 2021 07:57:33'	System	17 Jan 2021 13:57:37

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-01-24T09:46:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5d259de9-03c4-427d-a555-3e671f3735dd'	System	24 Jan 2021 15:47:08
User entered 'No (N)'	System	24 Jan 2021 15:47:08

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-01-24T09:46:58', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5d259de9-03c4-427d-a555-3e671f3735dd'	System	24 Jan 2021 15:47:08
User entered 'No (N)'	System	24 Jan 2021 15:47:08

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-01-24T09:47:04', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '5d259de9-03c4-427d-a555-3e671f3735dd' User entered '24 Jan 2021 09:47:04'	System	24 Jan 2021 15:47:08
	System	24 Jan 2021 15:47:08

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-02-01T05:06:57', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '75885e85-90ff-4a69-a78b-d94a302440be'	System	01 Feb 2021 11:07:06
User entered 'No (N)'	System	01 Feb 2021 11:07:06

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-02-01T05:07:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '75885e85-90ff-4a69-a78b-d94a302440be'	System	01 Feb 2021 11:07:06
User entered 'No (N)'	System	01 Feb 2021 11:07:06

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-02-01T05:07:01', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '75885e85-90ff-4a69-a78b-d94a302440be'	System	01 Feb 2021 11:07:06
User entered '01 Feb 2021 05:07:01'	System	01 Feb 2021 11:07:06

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-02-08T05:23:14', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '40a79ecf-f2fc-40d0-8c2d-468af75269b6'	System	08 Feb 2021 11:23:24
User entered 'No (N)'	System	08 Feb 2021 11:23:24

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-02-08T05:23:17', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '40a79ecf-f2fc-40d0-8c2d-468af75269b6'	System	08 Feb 2021 11:23:24
User entered 'No (N)'	System	08 Feb 2021 11:23:24

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-02-08T05:23:19', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '40a79ecf-f2fc-40d0-8c2d-468af75269b6'	System	08 Feb 2021 11:23:24
User entered '08 Feb 2021 05:23:19'	System	08 Feb 2021 11:23:24

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-02-18T07:13:56', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'ae60c172-0678-46bb-8710-b5f5670976b7'	System	18 Feb 2021 13:14:06
User entered 'No (N)'	System	18 Feb 2021 13:14:06

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-02-18T07:13:58', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'ae60c172-0678-46bb-8710-b5f5670976b7'	System	18 Feb 2021 13:14:06
User entered 'No (N)'	System	18 Feb 2021 13:14:06

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-02-18T07:14:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'ae60c172-0678-46bb-8710-b5f5670976b7'	System	18 Feb 2021 13:14:06
User entered '18 Feb 2021 07:14:00'	System	18 Feb 2021 13:14:06

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-02-21T08:15:41', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '286ef885-c8bf-46fe-8795-8c7e6fdf4cee'	System	21 Feb 2021 14:15:54
User entered 'No (N)'	System	21 Feb 2021 14:15:54

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-02-21T08:15:43', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '286ef885-c8bf-46fe-8795-8c7e6fdf4cee'	System	21 Feb 2021 14:15:54
User entered 'No (N)'	System	21 Feb 2021 14:15:54

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-02-21T08:15:50', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '286ef885-c8bf-46fe-8795-8c7e6fdf4cee'	System	21 Feb 2021 14:15:54
User entered '21 Feb 2021 08:15:50'	System	21 Feb 2021 14:15:54

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-03-01T05:21:38-06:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9a6c9981-6ffc-4db7-95e8-42011efedf01'	System	01 Mar 2021 11:21:46
User entered 'No (N)'	System	01 Mar 2021 11:21:46

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-03-01T05:21:41-06:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9a6c9981-6ffc-4db7-95e8-42011efedf01'	System	01 Mar 2021 11:21:46
User entered 'No (N)'	System	01 Mar 2021 11:21:46

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-03-01T05:21:44-06:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '9a6c9981-6ffc-4db7-95e8-42011efedf01' User entered '01 Mar 2021 05:21:44'	System	01 Mar 2021 11:21:46
	System	01 Mar 2021 11:21:46

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-03-07T07:19:45-06:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'aedac815-1503-4d4d-9e98-994db454c106'	System	07 Mar 2021 13:19:56
User entered 'No (N)'	System	07 Mar 2021 13:19:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-03-07T07:19:48-06:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'aedac815-1503-4d4d-9e98-994db454c106'	System	07 Mar 2021 13:19:56
User entered 'No (N)'	System	07 Mar 2021 13:19:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-03-07T07:19:51-06:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'aedac815-1503-4d4d-9e98-994db454c106'	System	07 Mar 2021 13:19:56
User entered '07 Mar 2021 07:19:51'	System	07 Mar 2021 13:19:56

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-03-15T06:21:10-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '77d1f41a-10b9-47a3-a8f7-a9b16740f077'	System	15 Mar 2021 11:21:21
User entered 'No (N)'	System	15 Mar 2021 11:21:21

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-03-15T06:21:13-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '77d1f41a-10b9-47a3-a8f7-a9b16740f077'	System	15 Mar 2021 11:21:21
User entered 'No (N)'	System	15 Mar 2021 11:21:21

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-03-15T06:21:15-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '77d1f41a-10b9-47a3-a8f7-a9b16740f077'	System	15 Mar 2021 11:21:21
User entered '15 Mar 2021 06:21:15'	System	15 Mar 2021 11:21:21

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-03-23T12:00:43-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6ac12a3a-d5ef-45e6-9fcc-b143fafbbe1c'	System	23 Mar 2021 17:01:30
User entered 'No (N)'	System	23 Mar 2021 17:01:30

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-03-23T12:00:46-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6ac12a3a-d5ef-45e6-9fcc-b143fafbbe1c'	System	23 Mar 2021 17:01:30
User entered 'No (N)'	System	23 Mar 2021 17:01:30

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-03-23T12:00:49-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '6ac12a3a-d5ef-45e6-9fcc-b143fafbbe1c'	System	23 Mar 2021 17:01:30
User entered '23 Mar 2021 12:00:49'	System	23 Mar 2021 17:01:30

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-03-28T08:04:21-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23a29686-a72d-4606-b9c1-d3afd9c3d594'	System	28 Mar 2021 13:04:27
User entered 'No (N)'	System	28 Mar 2021 13:04:27

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-03-28T08:04:22-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23a29686-a72d-4606-b9c1-d3afd9c3d594'	System	28 Mar 2021 13:04:27
User entered 'No (N)'	System	28 Mar 2021 13:04:27

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-03-28T08:04:25-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '23a29686-a72d-4606-b9c1-d3afd9c3d594'	System	28 Mar 2021 13:04:27
User entered '28 Mar 2021 08:04:25'	System	28 Mar 2021 13:04:27

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-04-04T08:07:21-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b246d2fa-33b9-418d-b3e7-24b95f90320c'	System	04 Apr 2021 13:07:34
User entered 'No (N)'	System	04 Apr 2021 13:07:34

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-04-04T08:07:25-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b246d2fa-33b9-418d-b3e7-24b95f90320c'	System	04 Apr 2021 13:07:34
User entered 'No (N)'	System	04 Apr 2021 13:07:34

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-04-04T08:07:27-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'b246d2fa-33b9-418d-b3e7-24b95f90320c' User entered '04 Apr 2021 08:07:27'	System	04 Apr 2021 13:07:34
	System	04 Apr 2021 13:07:34

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-04-11T08:10:35-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '80af3c3c-b629-48bf-a8f2-c97a94ee6b9e' User entered 'Yes (Y)'	System	11 Apr 2021 13:11:49
	System	11 Apr 2021 13:11:49

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-04-11T08:10:42-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '80af3c3c-b629-48bf-a8f2-c97a94ee6b9e'	System	11 Apr 2021 13:11:49
User entered 'No (N)'	System	11 Apr 2021 13:11:49

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-04-11T08:10:45-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '80af3c3c-b629-48bf-a8f2-c97a94ee6b9e' User entered 'No (N)'	System	11 Apr 2021 13:11:49
	System	11 Apr 2021 13:11:49

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-04-11T08:11:05-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '80af3c3c-b629-48bf-a8f2-c97a94ee6b9e'	System	11 Apr 2021 13:11:49
User entered 'Yes (Y)'	System	11 Apr 2021 13:11:49

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Please 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 (ba59af6f7bf7e24d)', Time: '2021-04-11T08:11:13-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '80af3c3c-b629-48bf-a8f2-c97a94ee6b9e'	System	11 Apr 2021 13:11:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Apr 2021 13:11:49

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-04-11T08:11:38-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '80af3c3c-b629-48bf-a8f2-c97a94ee6b9e'	System	11 Apr 2021 13:11:49
User entered '11 Apr 2021 08:11:38'	System	11 Apr 2021 13:11:49

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-04-18T08:12:04-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '82fa55ba-652f-418b-b444-ff7d47241687'	System	18 Apr 2021 13:12:13
User entered 'No (N)'	System	18 Apr 2021 13:12:13

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-04-18T08:12:08-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '82fa55ba-652f-418b-b444-ff7d47241687'	System	18 Apr 2021 13:12:13
User entered 'No (N)'	System	18 Apr 2021 13:12:13

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-04-18T08:12:10-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '82fa55ba-652f-418b-b444-ff7d47241687'	System	18 Apr 2021 13:12:13
User entered '18 Apr 2021 08:12:10'	System	18 Apr 2021 13:12:13

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-04-25T09:19:44-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '86a115df-8557-4d62-b303-b8de4152dfea' User entered 'No (N)'	System	25 Apr 2021 14:19:52
	System	25 Apr 2021 14:19:52

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-04-25T09:19:47-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '86a115df-8557-4d62-b303-b8de4152dfea' User entered 'No (N)'	System	25 Apr 2021 14:19:52

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-04-25T09:19:50-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '86a115df-8557-4d62-b303-b8de4152dfea' User entered '25 Apr 2021 09:19:50'	System	25 Apr 2021 14:19:52
	System	25 Apr 2021 14:19:52

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[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 (ba59af6f7bf7e24d)', Time: '2021-05-02T05:25:44-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a3c4bcba-2674-4ec6-a8af-c2b5ae86eb8c'	System	02 May 2021 10:26:42
User entered 'Yes (Y)'	System	02 May 2021 10:26:42

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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 (ba59af6f7bf7e24d)', Time: '2021-05-02T05:25:12-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a3c4bcba-2674-4ec6-a8af-c2b5ae86eb8c'	System	02 May 2021 10:26:42
User entered 'No (N)'	System	02 May 2021 10:26:42

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-05-02T05:26:06-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a3c4bcba-2674-4ec6-a8af-c2b5ae86eb8c'	System	02 May 2021 10:26:42
User entered 'No (N)'	System	02 May 2021 10:26:42

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-05-02T05:26:12-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a3c4bcba-2674-4ec6-a8af-c2b5ae86eb8c'	System	02 May 2021 10:26:42
User entered 'Yes (Y)'	System	02 May 2021 10:26:42

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please 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 (ba59af6f7bf7e24d)', Time: '2021-05-02T05:26:20-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a3c4bcba-2674-4ec6-a8af-c2b5ae86eb8c'	System	02 May 2021 10:26:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 May 2021 10:26:42

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-05-02T05:26:33-05:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: 'a3c4bcba-2674-4ec6-a8af-c2b5ae86eb8c'	System	02 May 2021 10:26:42
User entered '02 May 2021 05:26:33'	System	02 May 2021 10:26:42

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:35:04

US3322314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:35:04
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:35:04

US3322314

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:08:30

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 19:18:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-02-27T16:30:22-06:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8f1f72b8-6738-41c4-aa65-9dbaf4ac0e7a'	System	27 Feb 2021 22:30:30
User entered 'No (N)'	System	27 Feb 2021 22:30:30

US3322314

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:08:30

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:18:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ba59af6f7bf7e24d)', Time: '2021-02-27T16:30:29-06:00', User OID: 'PatientReportedOutcome (US3322314)', ODM File OID: '8f1f72b8-6738-41c4-aa65-9dbaf4ac0e7a'	System	27 Feb 2021 22:30:30
User entered '27 Feb 2021 16:30:29'	System	27 Feb 2021 22:30:30

US3322314

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 22:03:32

US3322314

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '01 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 22:03:32

US3322314

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 22:03:32

US3322314

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:30:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 22:03:32

US3322314

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
DataPoint Verified.		07 Apr 2021 21:30:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 22:03:15

US3322314

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:09:02
User entered 'I'	System	02 Dec 2020 22:03:15

US3322314

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:30:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Jan 2021 18:18:02

US3322314

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:30:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '04 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Jan 2021 18:18:02

US3322314

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:30:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Jan 2021 18:18:02

US3322314

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:30:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Jan 2021 18:18:02

US3322314

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:30:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Jan 2021 18:18:08

US3322314

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
User entered 'I'	System	05 Jan 2021 18:18:08

US3322314

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:31:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:10:12

US3322314

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:31:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '03 Feb 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:10:12

US3322314

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:31:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:10:12

US3322314

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:31:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:10:12

US3322314

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:31:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:10:00

US3322314

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
User entered 'I'	System	03 Feb 2021 22:10:00

US3322314

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:32:46
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:07:38
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:45:16

US3322314

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:32:46
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:07:38
User entered '08 Mar 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:45:16

US3322314

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:32:46
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:07:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:45:16

US3322314

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:32:46
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:07:38
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:45:16

US3322314

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
DataPoint Verified.		07 Apr 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:07:38
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:45:21

US3322314

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:00:54
User entered 'I'	System	10 Mar 2021 19:45:21

US3322314

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:33:32
User entered 'Yes (Y)'		02 Apr 2021 19:52:15

US3322314

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:33:32
User entered '02 Apr 2021'		02 Apr 2021 19:52:15

US3322314

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:33:32
User entered 'Clinic (Clinic)'		02 Apr 2021 19:52:15

US3322314

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	02 Apr 2021 19:52:15

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:38
User entered 'Yes (Y)'		02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:38
User entered '02 Apr 2021'		02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:38
User entered '10:15'		02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 10:15'	System	02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:38
User entered '98.0' F		02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:38
User entered 'Oral (Oral)'		02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:38
User entered empty.		02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:38
User entered '73'		02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:38
User entered '15'		02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:38
User entered '118'		02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:38
User entered '63'		02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 19:52:37

US3322314

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:41
User entered 'No (N)'		02 Apr 2021 19:52:41

US3322314

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:41
User entered empty.		02 Apr 2021 19:52:41

US3322314

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:49
User entered 'Yes (Y)'		02 Apr 2021 19:52:49

US3322314

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:49
User entered '02 Apr 2021'		02 Apr 2021 19:52:49

US3322314

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:35:49
User entered '10:33'		02 Apr 2021 19:52:49

US3322314

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 10:33'	System	02 Apr 2021 19:52:49

US3322314

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:36:39
User entered 'Yes (Y)'		02 Apr 2021 19:52:55

US3322314

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:30

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 19:52:55

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:30

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:41
DataPoint Verified.		07 Apr 2021 21:49:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '07 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:41:22

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:30

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:41
DataPoint Verified.		07 Apr 2021 21:49:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '12:00'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:41:22

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:30

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:41
User entered '07 Dec 2020 12:00'	System	08 Dec 2020 21:41:22

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:30

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:41
DataPoint Verified.		07 Apr 2021 21:49:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Safety Call (Safety Call)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:41:22

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:30

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:41
DataPoint Verified.		07 Apr 2021 21:49:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:41:22

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Day 1 (Day 1)'	Elisa Moralez (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '04 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User entered '%'	System	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Day 2 (Day 2)'	Elisa Moralez (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '05 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User entered '%'	System	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Day 3 (Day 3)'	Elisa Moralez (b) (4)	08 Dec 2020 21:44:48

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '06 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User entered '%'	System	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Day 4 (Day 4)'	Elisa Moralez (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '07 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered missing code ND - Not Done.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User entered '%'	System	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '98.1' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Day 5 (Day 5)'	Elisa Moralez (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User closed query 'Please add log lines for Telemedicine Contact 09-Dec-2020, 10Dec2020 and 11Dec2020 noted in source. Thank you!' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:00:59
Query 'Please add log lines for Telemedicine Contact 09-Dec-2020, 10Dec2020 and 11Dec2020 noted in source. Thank you!' answered with 'adding now, thank you!' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:19:40
User opened query 'Please add log lines for Telemedicine Contact 09-Dec-2020, 10Dec2020 and 11Dec2020 noted in source. Thank you!' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 21:48:42
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:54:29
User entered '08 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '99'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User entered '%'	System	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '97.6' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'None (None)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
DataPoint Verified.		07 Apr 2021 21:45:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Mild (Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:44:48

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
User entered 'Day 6 (Day 6)'	Elisa Moralez (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:13:58
User entered '09 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered '0'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:14:11
User entered '99'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User entered '%'	System	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:14:13
User entered '97.9' F	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:14:37
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:14:35
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:14:33
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:14:32
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:20:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
User entered 'Day 7 (Day 7)'	Elisa Moralez (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:15:11
User entered '10 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered '0'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:15:08
User entered '98'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User entered '%'	System	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:15:09
User entered '97.6' F	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:15:30
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:15:29
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:07

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
User entered 'Day 8 (Day 8)'	Elisa Moralez (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered '11 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered '0'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered '97'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User entered '%'	System	09 Apr 2021 14:21:36

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered '98' F	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:32:44
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 14:21:36

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:30

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:51
DataPoint Verified.		07 Apr 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '07 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:02

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:30

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:51
DataPoint Verified.		07 Apr 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:02

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:30

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:51
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:38:16
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 20:25:59
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'pending results, it will be entered once available ' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 19:43:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Dec 2020 15:55:46
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:55:45
Query 'Data is required. Please complete.' answered with 'not yet known' (Site from System).	Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:07
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 21:45:02
User entered empty.	Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:02

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:30

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:51
DataPoint Verified.		07 Apr 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '07 Dec 2020' reason for change: Data Entry Error	(b) (4)	
User entered '7 Dec 2020'	Frances Saubon (b) (4)	09 Dec 2020 19:43:25
	(b) (4)	
	Elisa Moralez (b) (4)	08 Dec 2020 21:45:02
	(b) (4)	

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Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:30

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:51
DataPoint Verified.		07 Apr 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Nasal Swab (Nasal Swab)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:02

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:30

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:51
DataPoint Verified.		07 Apr 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:02

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:30

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:51
DataPoint Verified.		07 Apr 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:02

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Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:30

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:51
DataPoint Verified.		07 Apr 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:02

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:30

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:51
DataPoint Verified.		07 Apr 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:02

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:30

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:51
User entered '0'	System	11 Dec 2020 20:25:59

US3322314

Folder: Covid-19 Assessment 07 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:08:30

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:55
DataPoint Verified.		07 Apr 2021 21:44:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	25 Jan 2021 19:01:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 19:01:17
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	25 Jan 2021 19:01:17
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 19:01:14
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:01:14
	(b) (4)	

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:30

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
User accepted default value 'Day 3 (Day 3)'	Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '09 Dec 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:30

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
User accepted default value 'Day 5 (Day 5)'	Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:30

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
User accepted default value 'Day 7 (Day 7)'	Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:30

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
User accepted default value 'Day 9 (Day 9)'	Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:30

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
User accepted default value 'Day 14 (Day 14)'	Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:30

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
User accepted default value 'Day 21 (Day 21)'	Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:30

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
User accepted default value 'Day 28 (Day 28)'	Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:13
DataPoint Verified.		07 Apr 2021 21:44:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:01:32

US3322314

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:18
DataPoint Verified.		07 Apr 2021 21:37:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:19

US3322314

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:18
DataPoint Verified.		07 Apr 2021 21:37:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 11:11:58
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'please see updated saliva collection page.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:00:42
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 05:58:28
User entered '07 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:19

US3322314

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:18
DataPoint Verified.		07 Apr 2021 21:37:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:45:19

US3322314

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:18
User entered 'SICKD1'	System	08 Dec 2020 21:45:19

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '07 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '10:52'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
User entered '07 Dec 2020 10:52'	System	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '66' in	(b) (4)	
	Elisa Moralez (b) (4)	08 Dec 2020 21:46:41
	(b) (4)	
DataPoint set to visible.	System	08 Dec 2020 21:45:19

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '192' lb	(b) (4) Elisa Moralez (b) (4)	08 Dec 2020 21:46:41
DataPoint set to visible.	(b) (4) System	08 Dec 2020 21:45:19

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '98.1' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Oral (Oral)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '97'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
User entered 'bpm'	System	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '16'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
User entered 'breaths/min'	System	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '121'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
User entered 'mmHg'	System	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
DataPoint Verified.		07 Apr 2021 21:43:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '75'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:23
User entered 'mmHg'	System	08 Dec 2020 21:46:41

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 16:10:23

US3322314

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 16:10:23

US3322314

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:28
DataPoint Verified.		07 Apr 2021 21:43:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:50

US3322314

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:10:28
DataPoint Verified.		07 Apr 2021 21:43:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '07 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:50

US3322314

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:08:30

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:06
DataPoint Verified.		07 Apr 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:56

US3322314

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:08:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:14:06
DataPoint Verified.		07 Apr 2021 21:44:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '07 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	08 Dec 2020 21:46:56

US3322314

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:01:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:15

US3322314

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:01:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '18 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:15

US3322314

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:01:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:15

US3322314

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 15:54:15

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '18 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:07:38
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:52:03

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:07:38
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:52:03

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '18 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 04:36:27
User entered 'mRNA-1273 (mRNA-1273)'	Elisa Moralez (b) (4)	18 Jan 2021 15:54:24
	(b) (4)	

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 04:36:27
User entered 'mRNA-1273 (mRNA-1273)'	Elisa Moralez (b) (4)	18 Jan 2021 15:54:24
	(b) (4)	

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:24

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	18 Jan 2021 15:54:24

US3322314

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered empty.	System	18 Jan 2021 15:54:24

US3322314

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:32

US3322314

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '18 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:32

US3322314

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '08:54'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:32

US3322314

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '18 Jan 2021 08:54'	System	18 Jan 2021 15:54:32

US3322314

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:39

US3322314

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '18 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:39

US3322314

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:30

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
DataPoint Verified.		07 Apr 2021 22:02:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '08:49'	(b) (4) Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:54:39

US3322314

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:30

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:45:00
User entered '18 Jan 2021 08:49'	System	18 Jan 2021 15:54:39

US3322314

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:08:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:29
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:56
Signature has been broken.	Elisa Moralez (b) (4)	06 Apr 2021 19:01:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	06 Apr 2021 19:01:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	20 Feb 2021 19:37:18

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 19:03:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 19:03:18
Data point term sent to Coder	System	06 Apr 2021 19:02:27
User entered 'Upper Respiratory Infection'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered '04 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User entered empty.	System	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered '11 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User entered empty.	System	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'l'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[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 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:33:33
User entered empty.	Elisa Moralez (b) (4)	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User entered '0'	System	06 Apr 2021 19:02:08

US3322314

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45
User entered 'I'	System	06 Apr 2021 19:02:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:55:45

US3322314

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:09
Reviewed for Safety.		07 Apr 2021 15:15:15
User entered 'USA-US060-2021-mRNA-1273-P301000011'	System	07 Apr 2021 15:15:05
User entered 'New'	(b) (4), (b) (6)	07 Apr 2021 15:15:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:11
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 19:04:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 19:04:21
Data point term sent to Coder	System	06 Apr 2021 19:03:30
User entered 'Transient ischemic attack'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:12
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

US3322314

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:14
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

US3322314

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:15
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:15:16
User entered '05 Apr 2021'	Elisa Moralez (b) (4)	06 Apr 2021 19:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:18
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

US3322314

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 19:03:15

US3322314

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:34:18
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		13 Apr 2021 14:36:20
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'per PI response, "per conversation with patient. He was discharged on 06APR2021 in the afternoon. Will need to received MR; ROI already signed by patient. Awaiting for Medical records to review."' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:00:04
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:59:32
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:59:32
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:29:09
DataPoint Verified.		07 Apr 2021 21:15:20
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
User closed query 'PV Query: Event was reported as resolved on 06 Apr 2021. Subject was given acetylsalicylic acid on 09 Apr 2021 for TIA. Please confirm event outcome and end date and update accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:25
Query 'PV Query: Event was reported as resolved on 06 Apr 2021. Subject was given acetylsalicylic acid on 09 Apr 2021 for TIA. Please confirm event outcome and end date and update accordingly.' answered with 'dates are correct per source for this AE, please clarify as to where the documentation of "acetylsalicylic acid" in question is, as there is no conmed record for it in source, and it is not in the narrative' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 18:52:59
User opened query 'PV Query: Event was reported as resolved on 06 Apr 2021. Subject was given acetylsalicylic acid on 09 Apr 2021 for TIA. Please confirm event outcome and end date and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 18:48:51
DataPoint Verified.		19 Apr 2021 14:34:16
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).		13 Apr 2021 14:37:30
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'per PI response, "per conversation with patient. He was discharged on 06APR2021 in the afternoon. Will need to received MR; ROI already signed by patient. Awaiting for Medical records to review."' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:00:08
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Apr 2021 18:59:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	12 Apr 2021 18:59:50
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Apr 2021 18:59:32
DataPoint Un-verified.	Elisa Moralez (b) (4)	12 Apr 2021 18:59:32
User entered '06 Apr 2021' reason for change: Data Entry Error	(b) (4)	
	Elisa Moralez (b) (4)	12 Apr 2021 18:59:32
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)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:28:50
		07 Apr 2021 21:15:21
User entered empty.	Elisa Moralez (b) (4)	06 Apr 2021 19:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:25
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	06 Apr 2021 22:49:46
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	06 Apr 2021 22:48:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 22:48:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:15:27
User entered '0'	Elisa Moralez (b) (4)	06 Apr 2021 19:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:17:38
User entered '0'	Elisa Moralez (b) (4)	06 Apr 2021 19:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:49:53
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:36:20
User entered '1' reason for change: Data Entry Error	Elisa Moralez (b) (4)	19 Apr 2021 20:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:17:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 17:49:57
DataPoint Un-verified.	Elisa Moralez (b) (4)	19 Apr 2021 20:36:20
	(b) (4)	
User entered '05 Apr 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4)	19 Apr 2021 20:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:17:40
User entered empty.	Elisa Moralez (b) (4)	06 Apr 2021 19:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:50:00
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:36:20
User entered '06 Apr 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:36:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:17:35
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:50:03
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:36:20
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:36:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:17:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:17:34
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:17:32
User entered '0'	Elisa Moralez (b) (4)	06 Apr 2021 19:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:17:31
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:29
User entered '1' reason for change: Data Entry Error		06 Apr 2021 22:49:46
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:35
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:37
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:38
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:08:30

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:34:33
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:35:13
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:35:13
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:15:39
User entered '1'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:34:37
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).		13 Apr 2021 14:42:32
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' answered with 'updating now, thank you' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:35:28
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:35:13
User entered '1' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:35:13
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:28:40
DataPoint Verified.		07 Apr 2021 21:17:27
User entered '0'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:17:26
User entered '0'	Elisa Moralez (b) (4)	06 Apr 2021 19:03:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:34:40
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:59:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 18:59:50
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:15:41
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:17:24
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
User closed query 'PV Re-Query: narrative states physician told subject that he "may be" experiencing a TIA; was a TIA confirmed? Please keep query open until medical records have been reviewed.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:29
Query 'PV Re-Query: narrative states physician told subject that he "may be" experiencing a TIA; was a TIA confirmed? Please keep query open until medical records have been reviewed.' answered with 'per PI, "Discharge summary was not included with records. It would have the discharge diagnoses or final diagnoses." therefore, the information is unavailable in the records. However, please do note that the updated narrative that includes ALL available information is in source, but will not fit into the EDC space provided. If there is something more we can do to make it clearer in EDC what happened, please let us know. Thank you!' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 20:35:34
User opened query 'PV Re-Query: narrative states physician told subject that he "may be" experiencing a TIA; was a TIA confirmed? Please keep query open until medical records have been reviewed.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 18:49:02
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' canceled (Site from Safety).		21 Apr 2021 18:48:29
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		21 Apr 2021 18:48:06

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: narrative states subject went to ER on 05 Apr 2021, and was still under evaluation on 06 Apr 2021; was the subject admitted to the hospital overnight? If so, please consider updating seriousness criteria ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 16:42:14
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		20 Apr 2021 16:42:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).		20 Apr 2021 16:42:07
Query 'PV Query: narrative states subject went to ER on 05 Apr 2021, and was still under evaluation on 06 Apr 2021; was the subject admitted to the hospital overnight? If so, please consider updating seriousness criteria ' answered with 'please see updated narrative, thank you, all applicable forms are being updated with available information' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:35:26
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'please see updated narrative, thank you, all applicable forms are being updated with available information' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:35:23

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'please updated narrative, thank you' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 20:34:48
User closed query 'PV Query: narrative states physician told subject that he "may be" experiencing a TIA; was a TIA confirmed? ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 14:43:52
Query 'PV Query: narrative states physician told subject that he "may be" experiencing a TIA; was a TIA confirmed? ' answered with 'per PI response, "Awaiting for Medical records to review."' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:00:35
User opened query 'PV Query: narrative states subject went to ER on 05 Apr 2021, and was still under evaluation on 06 Apr 2021; was the subject admitted to the hospital overnight? If so, please consider updating seriousness criteria ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:29:35
User opened query 'PV Query: narrative states physician told subject that he "may be" experiencing a TIA; was a TIA confirmed? ' (Site from Safety).		12 Apr 2021 16:29:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		12 Apr 2021 16:29:20
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).		12 Apr 2021 16:28:58

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:15:44
User entered 'Patient contacted study site via text message today to report he is being evaluated at the ER for suspected TIA (Transient Ischemic Attack). Patient contacted study site via text message today and reported experiencing vomiting on the morning of 05APR2021. Upon arrival to work on the same day at 7:11 AM, he began experiencing slurred speech and difficulty with ambulation. Patient was seen by his cardiologist at approximately 10:45 AM. His cardiologist subsequently sent him to the ER for further evaluation and management. Patient arrived to the ER around 11:30 AM. After evaluation by ER physician, patient was told that he may be experiencing a TIA. As of 06APR2021 at 10:33 AM, patient is still under evaluation. Will await further update from patient regarding status. Will also obtain medical records with labs and radiology findings.'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 22:48:49
User entered '0'	System	06 Apr 2021 19:03:15

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 19:03:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 20:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:29
User closed query 'Per source, subject received flu vaccine on 12-Nov-2020. Please consider adding to EDC. Thank you!' (Site from CRA).		07 Apr 2021 21:17:56
Query 'Per source, subject received flu vaccine on 12-Nov-2020. Please consider adding to EDC. Thank you!' answered with 'updated thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:49:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:27:01
User opened query 'Per source, subject received flu vaccine on 12-Nov-2020. Please consider adding to EDC. Thank you!' (Site from CRA).		07 Apr 2021 20:26:57
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	Abdeali Dalal (b) (4) (b) (4)	14 Sep 2020 16:34:39

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 20:58:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 20:58:49
Data point term sent to Coder	System	12 Apr 2021 19:37:03
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:36:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:54:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:38:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:38:43
Data point term sent to Coder	System	15 Sep 2020 14:37:48
User entered 'Advil'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:40:49
DataPoint Un-verified.	Elisa Moralez (b) (4)	12 Apr 2021 19:36:06
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	12 Apr 2021 19:36:06
User entered 'Injection site pain' reason for change: New Information	(b) (4) Elisa Moralez (b) (4)	12 Apr 2021 19:36:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:25:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria' answered with 'does not meet AE criteria, confirmed' (Site from DM).	Elisa Morales (b) (4)	30 Oct 2020 18:35:01
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:45:33
User entered 'pain at injection site'	Frances Saubon (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '200'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'mg (mg)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'once (ONCE)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Oral (ORAL)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '12 Sep 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '12 Sep 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
DataPoint Verified.		07 Apr 2021 20:31:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4) (b) (4)	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
User entered empty.	System	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
User entered empty.	System	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:40
User entered empty.	System	15 Sep 2020 14:37:25

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Sep 2020 04:47:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:47:36
Data point term sent to Coder	System	26 Sep 2020 18:36:30
User entered 'METOPROLOL ER'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:25:40
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to MH eCRF. ' answered with 'entered per updated source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:05:02
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:45:42
User entered 'PALPITATION'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '25'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'as needed (PRN)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'un Apr 2017'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	
User entered 'UN May 2017' reason for change: Data Entry Error	System	26 Sep 2020 18:36:32
User opened query 'End date is prior to start date. Please correct.' (Site from System).	Elisa Moralez (b) (4)	26 Sep 2020 18:36:32
User entered 'un Mar 2017'	(b) (4)	
	System	26 Sep 2020 18:36:20
	Elisa Moralez (b) (4)	26 Sep 2020 18:36:20
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
DataPoint Verified.		07 Apr 2021 20:31:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
User entered empty.	System	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
User entered empty.	System	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:43
User entered empty.	System	26 Sep 2020 18:36:20

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 20:44:22
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 20:44:22
Data point term sent to Coder	System	07 Apr 2021 20:43:09
User entered 'Influenza vaccine'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered 'preventative healthcare'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered 'l'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered 'Other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered 'injection'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered 'once (ONCE)'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered 'Intramuscular (INTRAMUSCULAR)'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered '12 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered '12 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:10:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User entered empty.	System	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User entered empty.	System	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:03:47
User entered empty.	System	07 Apr 2021 20:42:18

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:05:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:05:42
Data point term sent to Coder	System	12 Apr 2021 19:38:05
User entered 'Zinc'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Immunity'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '11'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:37:34
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'three times daily (TID)'	Elisa Moralez (b) (4)	12 Apr 2021 19:37:34
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:37:34
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '06 Dec 2020'	Elisa Moralez (b) (4)	12 Apr 2021 19:37:34
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '0'	Elisa Moralez (b) (4)	12 Apr 2021 19:37:34
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:37:34
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 19:37:34

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
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)	14 Apr 2021 09:13:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:13:54
Data point term sent to Coder	System	12 Apr 2021 19:39:06
User entered 'Cetirizine (Zyrtec)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:38:26

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4)	12 Apr 2021 19:38:26
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Allergies'	Elisa Moralez (b) (4)	12 Apr 2021 19:38:26
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '10'	Elisa Moralez (b) (4)	12 Apr 2021 19:38:26
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:38:26

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:38:26
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:38:26

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:38:26
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:38:26

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:38:26

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '07 Dec 2020'	Elisa Moralez (b) (4)	12 Apr 2021 19:38:26
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '0'	Elisa Moralez (b) (4)	12 Apr 2021 19:38:26
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:38:26

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:38:26
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4)	12 Apr 2021 19:38:26
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:38:26

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:38:26

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 19:38:26

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: MINERALS NOS;VITAMINS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 08:42:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 08:42:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:07
Data point term sent to Coder	System	16 Apr 2021 18:41:17
User closed query 'CDM-Coding: The trade name WAL-BORNE cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.	System	16 Apr 2021 18:41:12
' (Site from System).		
Query 'CDM-Coding: The trade name WAL-BORNE Elisa Moralez cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.	(b) (4)	16 Apr 2021 18:41:12
' answered with 'updated' (Site from System).		
User entered '(Vitamin A), (Vitamin C), (Vitamin E),Elisa Moralez (Magnesium), (Zinc), (Selenium), (Manganese), (Sodium), (Proprietary Herbal Extract blend), (Proprietary Amino Acid Blend) Wal-borne' reason for change: Data Entry Error	(b) (4)	16 Apr 2021 18:40:21
User opened query 'CDM-Coding: The trade name WAL-BORNE cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.	Coder Import (b) (4)	15 Apr 2021 08:04:42
' (Site from System).		
Data point term sent to Coder	System	12 Apr 2021 19:39:06
User entered 'Wal-borne'	Elisa Moralez (b) (4)	12 Apr 2021 19:39:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Supplement'	Elisa Moralez (b) (4)	12 Apr 2021 19:39:01
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User closed query 'Data is required. Please complete.' (Site from System).		19 Apr 2021 13:54:17
Query 'Data is required. Please complete.' answered with '600mcg/1000/13.5/40/8/15mcg/3/150/350/50 multiple units' (Site from System).	Elisa Moralez (b) (4) (b) (4)	16 Apr 2021 18:40:34
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 18:40:21
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Apr 2021 18:40:21
User entered '1000'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Other (OTHER)' reason for change:	Elisa Moralez (b) (4)	16 Apr 2021 18:40:21
Data Entry Error	(b) (4)	
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '600MCG/1000MG/13.5MG/40MG/8MG/15MCG/3 MG/150MG/350MG/50MG' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Apr 2021 18:41:05
User entered '600mcg/1000/13.5/40/8/15mcg/3/150/350/50' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Apr 2021 18:40:21
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'twice daily (BID)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:39:01
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '06 Dec 2020'	Elisa Moralez (b) (4)	12 Apr 2021 19:39:01
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '0'	Elisa Moralez (b) (4)	12 Apr 2021 19:39:01
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 19:39:01

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:02:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:02:27
Data point term sent to Coder	System	12 Apr 2021 19:40:09
User entered 'Aspirin'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Elevated Blood Pressure'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '324'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:39:41
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'once (ONCE)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:39:41
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '05 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '0'	Elisa Moralez (b) (4)	12 Apr 2021 19:39:41
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '05 Apr 2021'	Elisa Moralez (b) (4)	12 Apr 2021 19:39:41
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4)	12 Apr 2021 19:39:41
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:39:41

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:04:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:04:43
Data point term sent to Coder	System	12 Apr 2021 19:41:11
User entered 'Aspirin'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Transient ischemic attack'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '81'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:40:24
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '09 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '0'	Elisa Moralez (b) (4)	12 Apr 2021 19:40:24
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4)	12 Apr 2021 19:40:24
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 19:40:24

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: NEBIVOLOL HYDROCHLORIDE, PRODUCTSYNONYM: BYSTOLIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:48:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:48:01
Data point term sent to Coder	System	12 Apr 2021 19:41:12
User entered 'Bystolic(Nebivolol)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:56

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4)	12 Apr 2021 19:40:56
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Elevated blood pressure'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:56

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '10'	Elisa Moralez (b) (4)	12 Apr 2021 19:40:56
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:56

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:56

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'once (ONCE)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:56

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 19:40:56
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:56

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Apr 2021 19:40:56

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '09 Apr 2021'	Elisa Moralez (b) (4)	12 Apr 2021 19:40:56
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '0'	Elisa Moralez (b) (4)	12 Apr 2021 19:40:56
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4)	12 Apr 2021 19:40:56
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered '09 Apr 2021'	Elisa Moralez (b) (4)	12 Apr 2021 19:40:56
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 14:43:07
User entered 'No (N)'	Elisa Moralez (b) (4)	12 Apr 2021 19:40:56
	(b) (4)	

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:40:56

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:40:56

US3322314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:40:56

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:08:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:29
DataPoint Verified.		19 Apr 2021 14:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
DataPoint Un-verified.	(b) (4)	
	Elisa Moralez (b) (4)	12 Apr 2021 21:21:52
Signature has been broken.	(b) (4)	
	Elisa Moralez (b) (4)	12 Apr 2021 21:21:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Elisa Moralez (b) (4)	12 Apr 2021 21:21:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 20:32:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:54:29
	(b) (4)	
User entered 'No (N)'	Elisa Moralez (b) (4)	20 Feb 2021 19:37:39
	(b) (4)	

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:30

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
	(b) (4)	
Signature has been broken.	Elisa Moralez (b) (4)	19 Apr 2021 20:36:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
	(b) (4)	
User entered '05 Apr 2021'	Elisa Moralez (b) (4)	12 Apr 2021 21:22:05
	(b) (4)	

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered 'CT scan (No acute finding)'	Elisa Moralez (b) (4)	12 Apr 2021 21:22:05

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4)	12 Apr 2021 21:22:05

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:30

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 21:22:05

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:08:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered '05 Apr 2021'	Elisa Moralez (b) (4)	12 Apr 2021 21:22:13

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:08:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered 'MRI (No acute findings)'	Elisa Moralez (b) (4)	12 Apr 2021 21:22:13

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4)	12 Apr 2021 21:22:13

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:08:30

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 21:22:13

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:08:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered '09 Apr 2021'	Elisa Moralez (b) (4)	12 Apr 2021 21:22:25

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:08:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered 'EKG (unremarkable)'	Elisa Moralez (b) (4)	12 Apr 2021 21:22:25

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:08:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered 'Adverse Event (AE)'	Elisa Moralez (b) (4)	12 Apr 2021 21:22:25

US3322314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:08:30

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:45
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:31:30
User entered empty.	Elisa Moralez (b) (4)	12 Apr 2021 21:22:25

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'USA-US060-2021-MRNA-1273-P301000011'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Yes (Y)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:59:55
Reviewed for Safety.		20 Apr 2021 16:33:50
Un-reviewed for Safety.	System	19 Apr 2021 20:36:20
DataPoint Un-verified.	System	19 Apr 2021 20:36:20
User entered 'Yes (Y)'	System	19 Apr 2021 20:36:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Yes (Y)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Veronica'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Fragoso'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered '6550 Mapleridge Street'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Houston'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'TX'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered '77081'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:33:50
DataPoint Verified.		07 Apr 2021 21:14:30
User entered 'US'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 14:21:45
User entered '3'	System	20 Apr 2021 16:33:47
User entered '2'	System	13 Apr 2021 14:47:44
User entered '1'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'USA-US060-2021-MRNA-1273-P301000011'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Yes (Y)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:59:55
Reviewed for Safety.		20 Apr 2021 16:33:50
Un-reviewed for Safety.	System	19 Apr 2021 20:36:20
DataPoint Un-verified.	System	19 Apr 2021 20:36:20
User entered 'Yes (Y)'	System	19 Apr 2021 20:36:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Yes (Y)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Veronica'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Fragoso'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered '6550 Mapleridge Street'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Houston'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'TX'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered '77081'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:33:50
DataPoint Verified.		07 Apr 2021 21:14:30
User entered 'US'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 14:21:45
User entered '3'	System	20 Apr 2021 16:33:47
User entered '2'	System	13 Apr 2021 14:47:44
User entered '1'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:08:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
User entered '07/Apr/2021 08:15'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:08:30

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.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:33:50
DataPoint Verified.		07 Apr 2021 21:14:30
User entered '1' reason for change: Data Entry Error		07 Apr 2021 15:15:58
User entered '0'		07 Apr 2021 15:15:44

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'USA-US060-2021-MRNA-1273-P301000011'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Yes (Y)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:59:55
Reviewed for Safety.		20 Apr 2021 16:33:50
Un-reviewed for Safety.	System	19 Apr 2021 20:36:20
DataPoint Un-verified.	System	19 Apr 2021 20:36:20
User entered 'Yes (Y)'	System	19 Apr 2021 20:36:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Yes (Y)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Veronica'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Fragoso'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered '6550 Mapleridge Street'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Houston'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'TX'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered '77081'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
Reviewed for Safety.	(b) (4) (u) (+), (b) (6)	20 Apr 2021 16:33:50
DataPoint Verified.		07 Apr 2021 21:14:30
User entered 'US'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 14:21:45
User entered '3'	System	20 Apr 2021 16:33:47
User entered '2'	System	13 Apr 2021 14:47:44
User entered '1'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:08:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:47:52
User entered '13/Apr/2021 07:47'	System	13 Apr 2021 14:47:44

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:08:30

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.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:33:50
DataPoint Verified.		19 Apr 2021 14:47:52
User entered '1'		13 Apr 2021 14:47:44

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'USA-US060-2021-MRNA-1273-P301000011'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Yes (Y)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	21 Apr 2021 14:59:55
Reviewed for Safety.		20 Apr 2021 16:33:50
Un-reviewed for Safety.	System	19 Apr 2021 20:36:20
DataPoint Un-verified.	System	19 Apr 2021 20:36:20
User entered 'Yes (Y)'	System	19 Apr 2021 20:36:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Yes (Y)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Veronica'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Fragoso'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered '6550 Mapleridge Street'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Houston'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'TX'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered '77081'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	20 Apr 2021 16:33:50
DataPoint Verified.		07 Apr 2021 21:14:30
User entered 'US'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 14:21:45
User entered '3'	System	20 Apr 2021 16:33:47
User entered '2'	System	13 Apr 2021 14:47:44
User entered '1'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:08:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:50:44
User entered '20/Apr/2021 12:33'	System	20 Apr 2021 16:33:47

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:08:30

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.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 17:50:44
Reviewed for Safety.		20 Apr 2021 16:33:50
User entered 'I'		20 Apr 2021 16:33:47

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'USA-US060-2021-MRNA-1273-P301000011'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Yes (Y)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:59:55
Reviewed for Safety.		20 Apr 2021 16:33:50
Un-reviewed for Safety.	System	19 Apr 2021 20:36:20
DataPoint Un-verified.	System	19 Apr 2021 20:36:20
User entered 'Yes (Y)'	System	19 Apr 2021 20:36:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'No (N)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Yes (Y)'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Veronica'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Fragoso'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered '6550 Mapleridge Street'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'Houston'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered 'TX'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:30
Reviewed for Safety.		07 Apr 2021 15:15:36
User entered '77081'	System	07 Apr 2021 15:15:05

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:33:50
DataPoint Verified.		07 Apr 2021 21:14:30
User entered 'US'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 14:21:45
User entered '3'	System	20 Apr 2021 16:33:47
User entered '2'	System	13 Apr 2021 14:47:44
User entered '1'	System	07 Apr 2021 15:15:58

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:08:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:10:10
User entered '22/Apr/2021 10:21'	System	22 Apr 2021 14:21:45

US3322314

Folder: SAE USA-US060-2021-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:08:30

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.	Veronica Fragoso (b) (4)	23 Apr 2021 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:10:10
User entered 'I'		22 Apr 2021 14:21:45