

US3242314 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:14:28

All time stamps listed in this document are displayed in GMT

US3242314

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 18:41:13

Generated On: 09 Jun 2021 16:14:28

Participant ID

US3242314

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

US3242314

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

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

Visit date (dd MMM yyyy)	10 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
------------	------

US3242314

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
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

US3242314

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Date of Informed Consent (*dd MMM yyyy*) 10 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

US3242314

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3242314

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Were any significant conditions reported?

Yes ☒
No ☐

US3242314

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242314

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3242314

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242314

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Condition	PERENNIAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242314

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Condition	CHRONIC KIDNEY DISEASE, STAGE 2
Start date (dd MMM yyyy)	01 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3242314

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	27 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3242314

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Condition	ELEVATED PROSTATE SPECIFIC ANTIGEN
Start date (dd MMM yyyy)	27 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242314

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	03 AUG 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3242314

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:23 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:23
Height (<i>xxx.x</i>)	68 in
Weight (<i>xxx.x</i>)	214 lb
BMI (<i>xxx.x</i>)	32.60662 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)	

US3242314

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3242314

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

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

PLAYS GOLF WITH 20 OTHER
PP, VOLUNTEERS AT (b) (6)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

19 of 1990

US3242314

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

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	False
Specify	

US3242314

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

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

Visit date (dd MMM yyyy)	10 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
------------	--------

US3242314

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 189759

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 ☒

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Height	ND - Not Done
Weight	ND - Not Done

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

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)	10 SEP 2020
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:37
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:50
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3242314

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

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.

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 12:20 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 12:20

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

US3242314

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 10 SEP 2020

Collection time (00:00-23:59) 11:43 (24 HR)

Collection date and time (derived) 10 SEP 2020 11:43

US3242314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:43	10 SEP 2020 11:43
Nasopharyngeal Swab 2	No		

US3242314

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

96.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp 10 SEP 2020 12:54

PC Open Date & Time 10 SEP 2020 12:40

PC Close Date & Time 10 SEP 2020 15:10

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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 97.2 °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 10 SEP 2020 21:16

PC Open Date & Time 10 SEP 2020 16:05

PC Close Date & Time 11 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

11 SEP 2020 22:27

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 21:31

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 23:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

14 SEP 2020 23:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 22:40

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 03:05

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

10 SEP 2020 12:55

PC Open Date & Time

10 SEP 2020 12:40

PC Close Date & Time

10 SEP 2020 15:10

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

10 SEP 2020 21:17

PC Open Date & Time

10 SEP 2020 16:05

PC Close Date & Time

11 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

11 SEP 2020 22:28

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

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)

8

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 21:33

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

4

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 23:23

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

14 SEP 2020 23:16

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

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

15 SEP 2020 22:39

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

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 03:05

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 12:56
PC Open Date & Time	10 SEP 2020 12:40
PC Close Date & Time	10 SEP 2020 15:10

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 21:18
PC Open Date & Time	10 SEP 2020 16:05
PC Close Date & Time	11 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

51 of 1990

EAB) (1725)

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 22:28
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

53 of 1990

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:33
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

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 ☒

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 23:24
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

57 of 1990

EAB) (1725)

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 23:17
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 1990

EAB) (1725)

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 22:40
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

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

61 of 1990

EAB) (1725)

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 03:06
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3242314

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242314

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242314

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:41:15

Generated On: 09 Jun 2021 16:14:28

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
------------	--------

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Apr 2021 13:04:11

Generated On: 09 Jun 2021 16:14:28

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)	09 OCT 2020
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 08:05
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Apr 2021 13:04:11

Generated On: 09 Jun 2021 16:14:28

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)	09 OCT 2020
Time of assessment (00:00-23:59)	09:32 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 09:32
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3242314

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:41:15

Generated On: 09 Jun 2021 16:14:28

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.

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Apr 2021 13:04:11

Generated On: 09 Jun 2021 16:14:28

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) 09:01 (24 HR)

Treatment Date and Time (derived) 09 OCT 2020 09:01

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

US3242314

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:41:15

Generated On: 09 Jun 2021 16:14:28

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 9 OCT 2020

Collection time (00:00-23:59) 08:32 (24 HR)

Collection date and time (derived) 9 OCT 2020 08:32

US3242314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Apr 2021 13:04:11

Generated On: 09 Jun 2021 16:14:28

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	08:25	09 OCT 2020 08:25
Nasopharyngeal Swab 2	No		

US3242314

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐
No ☒

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

PC Time Stamp 09 OCT 2020 09:29

PC Open Date & Time 09 OCT 2020 09:21

PC Close Date & Time 09 OCT 2020 11:51

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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 97.8 °F

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

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

PC Time Stamp	09 OCT 2020 21:22
PC Open Date & Time	09 OCT 2020 12:46
PC Close Date & Time	10 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

98.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

10 OCT 2020 21:06

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 00:02

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 22:46

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 21:50

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 05:57

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 21:41

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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 09:30

PC Open Date & Time

09 OCT 2020 09:21

PC Close Date & Time

09 OCT 2020 11:51

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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 21:23

PC Open Date & Time

09 OCT 2020 12:46

PC Close Date & Time

10 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

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 21:07

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

12 OCT 2020 00:02

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

12 OCT 2020 22:47

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

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 21:50

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

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

15 OCT 2020 05:58

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

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 21:41

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 09:30
PC Open Date & Time	09 OCT 2020 09:21
PC Close Date & Time	09 OCT 2020 11:51

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 21:23
PC Open Date & Time	09 OCT 2020 12:46
PC Close Date & Time	10 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

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 ☒

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 21:09
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

99 of 1990

EAB) (1725)

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

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)

101 of 1990

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 22:48
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

103 of 1990

EAB) (1725)

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 21:51
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

105 of 1990

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 05:58
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

107 of 1990

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 21:42
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3242314

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242314

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242314

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242314

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:41:15

Generated On: 09 Jun 2021 16:14:28

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

Visit date (dd MMM yyyy)	5 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
------------	--------

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:41:15

Generated On: 09 Jun 2021 16:14:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 NOV 2020
Time of assessment (00:00-23:59)	08:19 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 08:19
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242314

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:41:15

Generated On: 09 Jun 2021 16:14:28

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.

US3242314

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:41:15

Generated On: 09 Jun 2021 16:14:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 NOV 2020
Collection time (00:00-23:59)	08:48 (24 HR)
Collection date and time (derived)	5 NOV 2020 08:48

US3242314

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:15

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 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	11 NOV 2020 10:32:28
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

17 NOV 2020 17:33:14

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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	24 NOV 2020 15:12:12
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 11:43:09

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 07:34:26
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 16:44:06
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

19 DEC 2020 16:28:09

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 08:09:06

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

02 JAN 2021 05:50:52

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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	09 JAN 2021 06:34:53
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 08:54:06

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

23 JAN 2021 10:15:52

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	30 JAN 2021 05:52:32
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

06 FEB 2021 07:31:20

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 FEB 2021 04:40:35
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

20 FEB 2021 07:30:43

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 19:48:13

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 06:52:20

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

14 MAR 2021 08:56:43

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 07:14:35

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

27 MAR 2021 11:59:53

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

03 APR 2021 06:00:26

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 05:51:16

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

17 APR 2021 07:10:03

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

26 APR 2021 08:24:02

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 18:01:12

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 <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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission	
Patient Cloud Open Date & Time	08 MAY 2021 00:01
Patient Cloud Close Date & Time	12 MAY 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 250

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 <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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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="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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	18 AUG 2021 23:59
---	-------------------

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

Patient Cloud Open Date & Time	23 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	27 OCT 2021 23:59
---	-------------------

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

Patient Cloud Open Date & Time	13 NOV 2021 00:01
--	-------------------

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐ Yes ☐

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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="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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 <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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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="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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission	
Patient Cloud Open Date & Time	06 AUG 2022 00:01
Patient Cloud Close Date & Time	10 AUG 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2022 00:01
--	-------------------

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2022 00:01
Patient Cloud Close Date & Time	21 SEP 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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="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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

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

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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="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"/>

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3242314

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:14:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 19:48:29

US3242314

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3242314

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3242314

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3242314

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 21:18:31

Generated On: 09 Jun 2021 16:14:28

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

Visit date (dd MMM yyyy)	07 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
------------	--------

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 21:18:31

Generated On: 09 Jun 2021 16:14:28

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3242314

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 21:18:31

Generated On: 09 Jun 2021 16:14:28

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.

US3242314

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 21:18:31

Generated On: 09 Jun 2021 16:14:28

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 07 APR 2021

Collection time (00:00-23:59) 08:15 (24 HR)

Collection date and time (derived) 07 APR 2021 08:15

US3242314

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:18:31

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242314

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242314

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:14:28

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3242314

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:41:14

Generated On: 09 Jun 2021 16:14:28

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 12 JAN 2021

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

Folder OID UNBLND_DECIDE

US3242314

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

Form: Unblinding

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Date of updated informed consent (dd MMM yyyy) 12 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) 12 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 _____

US3242314

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:41:13

Generated On: 09 Jun 2021 16:14:28

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 12 JAN 2021

Collection time (00:00-23:59) 08:33 (24 HR)

Collection date and time (derived) 12 JAN 2021 08:33

US3242314

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 18:41:13

Generated On: 09 Jun 2021 16:14:28

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

Collection date (dd MMM yyyy)	12 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	08:28
---------------------------------	-------

Collection Date and Time (derived)	12 JAN 2021 08:28
------------------------------------	-------------------

US3242314

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 18:41:13

Generated On: 09 Jun 2021 16:14:28

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

AEID	USA-US067-2020-MRNA-1273-P30 1000012
Adverse event	PROSTATIC ADENOCARCINOMA (GLEASON SCORE 3+4+=7)
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)	06 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

329 of 1990

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

SUBJECT WENT TO UROLOGIST
ON 22OCT2020. PROSTATE
BIOPSY WAS SCHEDULED DUE
TO INCREASING PSA LEVELS
OVER LAST SEVERAL YEARS.
MEDICAL RECORDS RECEIVED
TO REVEAL PROSTATIC
ADENOCARCINOMA. PER PI,
THIS DOES MEET SERIOUS
CRITERIA. WILL FOLLOW
SUBJECT FOR PLAN OF
TREATMENT.
SUBJECT STATES HE HAD
SURGICAL CONSULT ON
30NOV2020 AND WILL HAVE
RADIATION CONSULT ON
03DEC2020, HE WILL THEN
DETERMINE THE BEST COURSE
OF TREATMENT.
UPDATE: RADIATION AND
SURGICAL CONSULT
COMPLETED AND SUBJECT IS
SCHEDULED FOR
PROSTATECTOMY 1/27/2021.

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)	
--	--

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 18:41:13

Generated On: 09 Jun 2021 16:14:28

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

Yes ☒

No ☐

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

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

333 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1994
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"/>	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

335 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1994
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"/>	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 125

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)

337 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

339 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

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

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL AND PERENNIAL
ALLERGIC RHINITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

341 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2016
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"/>

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication CHILLS / BODY ACHES

Dose per administration 1000

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)

343 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

	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)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 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"/>

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Name of Medication ALFUZOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR PROSTATE
BIOPSY

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

347 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

	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)	2 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐
No ☒

Indication POST PROCEDURE,
PROSTATECTOMY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

349 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

	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)	28 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 FEB 2021	
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"/>

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☒
No ☐

Indication POST PROCEDURE,
PROPHYLAXIS FOR INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

351 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 11 Mar 2021 00:29:01

Generated On: 09 Jun 2021 16:14:28

	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)	3 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
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"/>

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 18:41:13

Generated On: 09 Jun 2021 16:14:28

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Feb 2021 18:41:13

Generated On: 09 Jun 2021 16:14:28

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 NOV 2020	PROSTATE BIOPSY	Adverse Event	
27 JAN 2021	PROSTATECTOMY	Adverse Event	

US3242314

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:14:28

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3242314

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:14:28

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 ☐

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 13:04:11

Generated On: 09 Jun 2021 16:14:28

SAEID	USA-US067-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 13:04:11

Generated On: 09 Jun 2021 16:14:28

SAEID	USA-US067-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/NOV/2020 20:23
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

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 13:04:11

Generated On: 09 Jun 2021 16:14:28

SAEID	USA-US067-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/DEC/2020 13:09
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

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 13 Apr 2021 13:04:11

Generated On: 09 Jun 2021 16:14:28

SAEID	USA-US067-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/JAN/2021 21:19
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

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 13 Apr 2021 13:04:11

Generated On: 09 Jun 2021 16:14:28

SAEID	USA-US067-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/MAR/2021 11:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 13 Apr 2021 13:04:11

Generated On: 09 Jun 2021 16:14:28

SAEID	USA-US067-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/APR/2021 06:17
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

US3242314 (Prod: Clinical Research Atlanta - ERN-PPDS)

US3242314

Form: Participant Creation

Generated On: 09 Jun 2021 16:14:28

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'US3242314'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:49:29

US3242314

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:22:57

US3242314

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:49:30

US3242314

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	10 Sep 2020 15:22:57

US3242314

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'SCRN'	(b) (4), (b) (6) System	10 Sep 2020 15:22:57

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:49:31

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '75'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'YEARS'	(b) (4), (b) (6) System	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '75'	(b) (4), (b) (6) System	10 Sep 2020 15:23:29

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Male (M)'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'I'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:28

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:13

US3242314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:28

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:29

US3242314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Sep 2020'	(b) (4), (b) (6) System	10 Sep 2020 15:23:29

US3242314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '2020'	(b) (4), (b) (6) System	10 Sep 2020 15:23:29

US3242314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:28

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Amendment 3 (3)'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:29

US3242314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:29

US3242314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:28

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:23:29

US3242314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:23:29

US3242314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:23:29

US3242314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:49:30

US3242314

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:28

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'I'	(b) (4), (b) (6) System	10 Sep 2020 15:24:34

US3242314

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:24:34

US3242314

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:14:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:24:41

US3242314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:27:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:27:48
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 15:26:53
User entered 'Hypertension'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:31

US3242314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Un UNK 1994'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:31

US3242314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:31

US3242314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:31

US3242314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:26:31

US3242314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:31

US3242314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Jan 1994'	(b) (4), (b) (6) System	10 Sep 2020 15:26:31

US3242314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '1994'	(b) (4), (b) (6) System	10 Sep 2020 15:26:31

US3242314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:26:31

US3242314

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:26:31

US3242314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:27:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:27:47
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 15:26:53
User entered 'Hypothyroidism'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:40

US3242314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Un UNK 2000'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:40

US3242314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:40

US3242314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:40

US3242314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:26:40

US3242314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:40

US3242314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Jan 2000'	(b) (4), (b) (6) System	10 Sep 2020 15:26:40

US3242314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '2000'	(b) (4), (b) (6) System	10 Sep 2020 15:26:40

US3242314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:26:40

US3242314

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:26:40

US3242314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User coded data point as SOC: Eye disorders, HLGT: Ocular haemorrhages and vascular disorders NEC, HLT: Optic nerve bleeding and vascular disorders, PT: Optic ischaemic neuropathy, LLT: Ischemic optic neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:27:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:27:46
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 15:26:53
User entered 'Ischemic optic neuropathy'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:52

US3242314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'UN Jan 2020'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:52

US3242314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:52

US3242314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:52

US3242314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:26:52

US3242314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:26:52

US3242314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Jan 2020'	(b) (4), (b) (6) System	10 Sep 2020 15:26:52

US3242314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '2020'	(b) (4), (b) (6) System	10 Sep 2020 15:26:52

US3242314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:26:52

US3242314

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:26:52

US3242314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:28:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:28:54
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 15:27:54
User entered 'Obesity'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:00

US3242314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Un UNK 2016'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:00

US3242314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:00

US3242314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:00

US3242314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:27:00

US3242314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:00

US3242314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Jan 2016'	(b) (4), (b) (6) System	10 Sep 2020 15:27:00

US3242314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '2016'	(b) (4), (b) (6) System	10 Sep 2020 15:27:00

US3242314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:27:00

US3242314

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:27:00

US3242314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:28:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:28:53
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 15:27:56
User entered 'Seasonal allergic rhinitis'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:12

US3242314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Un UNK 2016'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:12

US3242314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:12

US3242314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:12

US3242314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:27:12

US3242314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:12

US3242314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Jan 2016'	(b) (4), (b) (6) System	10 Sep 2020 15:27:12

US3242314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '2016'	(b) (4), (b) (6) System	10 Sep 2020 15:27:12

US3242314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:27:12

US3242314

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:27:12

US3242314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis perennial, LLT: Perennial allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:28:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 15:28:52
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 15:27:56
User entered 'Perennial allergic rhinitis'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:29

US3242314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Un UNK 2016'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:29

US3242314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:29

US3242314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:29

US3242314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:27:29

US3242314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:27:29

US3242314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Jan 2016'	(b) (4), (b) (6) System	10 Sep 2020 15:27:29

US3242314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '2016'	(b) (4), (b) (6) System	10 Sep 2020 15:27:29

US3242314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:27:29

US3242314

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 15:27:29

US3242314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:14:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User coded data point as SOC: Renal and urinary disorders, HLG: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 2 - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 06:21:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 06:21:46
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 13:59:15
User entered 'Chronic Kidney Disease, Stage 2'	Donna Toepfer (b) (4)	13 Nov 2020 13:58:45

US3242314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '01 Jun 2019'	Donna Toepfer (b) (4)	13 Nov 2020 13:58:45

US3242314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 13:58:45

US3242314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:14:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 13:58:45

US3242314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 13:58:45

US3242314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:14:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 13:58:45

US3242314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Jun 2019'	(b) (4), (b) (6) System	13 Nov 2020 13:58:45

US3242314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '2019'	(b) (4), (b) (6) System	13 Nov 2020 13:58:45

US3242314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 13:58:45

US3242314

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 13:58:45

US3242314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:14:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 13:59:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 13:59:45
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 13:59:15
User entered 'Benign Prostatic hyperplasia'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:03

US3242314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '27 Jun 2019'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:03

US3242314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:14:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:03

US3242314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:14:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:03

US3242314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 13:59:03

US3242314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:14:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:03

US3242314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Jun 2019'	(b) (4), (b) (6) System	13 Nov 2020 13:59:03

US3242314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '2019'	(b) (4), (b) (6) System	13 Nov 2020 13:59:03

US3242314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 13:59:03

US3242314

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 13:59:03

US3242314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:14:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User coded data point as SOC: Investigations, HLT: Cytogenetic investigations, HLT: Cell marker analyses, PT: Prostatic specific antigen increased, LLT: Elevated prostate specific antigen [PSA] - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 14:16:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 14:16:44
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 14:00:15
User entered 'Elevated Prostate Specific Antigen'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:21

US3242314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '27 Jun 2019'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:21

US3242314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:21

US3242314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:14:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:21

US3242314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 13:59:21

US3242314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:14:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:21

US3242314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Jun 2019'	(b) (4), (b) (6) System	13 Nov 2020 13:59:21

US3242314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '2019'	(b) (4), (b) (6) System	13 Nov 2020 13:59:21

US3242314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 13:59:21

US3242314

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 13:59:21

US3242314

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:14:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 14:01:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 14:01:45
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 14:00:15
User entered 'Erectile Dysfunction'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:36

US3242314

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '03 Aug 2017'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:36

US3242314

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:36

US3242314

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:14:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:36

US3242314

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 13:59:36

US3242314

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:14:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 13:59:36

US3242314

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'Aug 2017'	(b) (4), (b) (6) System	13 Nov 2020 13:59:36

US3242314

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '2017'	(b) (4), (b) (6) System	13 Nov 2020 13:59:36

US3242314

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 13:59:36

US3242314

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 13:59:36

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '10:23'	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '10 Sep 2020 10:23'	(b) (4), (b) (6) System	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '68' in	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25
DataPoint set to visible.	System	10 Sep 2020 15:24:34

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '214' lb	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25
DataPoint set to visible.	System	10 Sep 2020 15:24:34

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered '32.60662'	(b) (4), (b) (6)	
	System	10 Sep 2020 16:04:25
DataPoint set to visible.	System	10 Sep 2020 15:24:34

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	10 Sep 2020 16:04:25
DataPoint set to visible.	System	10 Sep 2020 15:24:34

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'bpm'	(b) (4), (b) (6) System	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'breaths/min'	(b) (4), (b) (6) System	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'mmHg'	(b) (4), (b) (6) System	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
User entered 'mmHg'	(b) (4), (b) (6) System	10 Sep 2020 16:04:25

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 09:03:16

US3242314

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 09:03:16

US3242314

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:28:37

US3242314

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	10 Sep 2020 15:28:37

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'plays golf with 20 other pp, volunteers at (b) (6) '	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'I'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:03:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 15:29:35

US3242314

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 15:30:06

US3242314

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	10 Sep 2020 15:30:06

US3242314

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	10 Sep 2020 15:30:06

US3242314

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'VISIT1'	(b) (4), (b) (6) System	10 Sep 2020 15:30:06

US3242314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:44:41

US3242314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:28

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '189759'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:44:41

US3242314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:28

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:44:41

US3242314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:28

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:30:22

US3242314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:28

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:30:22

US3242314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:28

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:30:22

US3242314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:28

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:30:22

US3242314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:28

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:30:22

US3242314

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:28

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'No (N)'	Erynn McKinley (b) (4)	23 Sep 2020 19:11:47
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:57:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:57:58

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered missing code ND - Not Done.	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered missing code ND - Not Done.	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered missing code ND - Not Done.	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered missing code ND - Not Done.	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '10 Sep 2020'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '10:37'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered '10 Sep 2020 10:37'	(b) (4), (b) (6) System	10 Sep 2020 17:35:21

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '97.3' F	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered empty.	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '64'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'bpm'	(b) (4), (b) (6) System	10 Sep 2020 17:35:21

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '14'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'breaths/min'	(b) (4), (b) (6) System	10 Sep 2020 17:35:21

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '138'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'mmHg'	(b) (4), (b) (6) System	10 Sep 2020 17:35:21

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '72'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'mmHg'	(b) (4), (b) (6) System	10 Sep 2020 17:35:21

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered missing code ND - Not Done.	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered missing code ND - Not Done.	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '10 Sep 2020'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '12:50'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered '10 Sep 2020 12:50'	(b) (4), (b) (6) System	10 Sep 2020 17:35:21

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '97.5' F	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered empty.	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '60'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'bpm'	(b) (4), (b) (6) System	10 Sep 2020 17:35:21

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '16'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'breaths/min'	(b) (4), (b) (6) System	10 Sep 2020 17:35:21

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '134'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'mmHg'	(b) (4), (b) (6) System	10 Sep 2020 17:35:21

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '72'	Erynn McKinley (b) (4)	10 Sep 2020 17:35:21
	(b) (4)	

US3242314

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'mmHg'	(b) (4), (b) (6) System	10 Sep 2020 17:35:21

US3242314

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:24

US3242314

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:07:24

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:23:29

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:23:29

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:23:29

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	10 Sep 2020 16:23:29

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '12:20'	Donna Toepfer (b) (4)	10 Sep 2020 16:23:29

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered '10 Sep 2020 12:20'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	10 Sep 2020 16:23:29

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'ONCE'	System	10 Sep 2020 16:23:29

US3242314

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:09:22

US3242314

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	10 Sep 2020 16:09:22

US3242314

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '11:43'	Donna Toepfer (b) (4)	10 Sep 2020 16:09:22

US3242314

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered '10 Sep 2020 11:43'	(b) (4), (b) (6) System	10 Sep 2020 16:09:22

US3242314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:14:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '10 Sep 2020'	Donna Toepfer (b) (4)	10 Sep 2020 16:09:34

US3242314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	10 Sep 2020 16:09:34

US3242314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:09:34

US3242314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered '11:43'	Donna Toepfer (b) (4)	10 Sep 2020 16:09:34

US3242314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered '10 Sep 2020 11:43'	(b) (4), (b) (6) System	10 Sep 2020 16:09:34

US3242314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	10 Sep 2020 16:09:34

US3242314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:09:34

US3242314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:09:34

US3242314

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 16:09:34

US3242314

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:29:16
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:09:38

US3242314

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'I'	(b) (4), (b) (6) System	10 Sep 2020 16:09:38

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:54:09', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ec9bef7c-fa98-4f2b-9364-0415d52af7f3'	(b) (4), (b) (6)	
	System	10 Sep 2020 16:54:38
User entered 'Yes (Y)'	System	10 Sep 2020 16:54:38

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:54:17', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ec9bef7c-fa98-4f2b-9364-0415d52af7f3' User entered '96.4'	(b) (4), (b) (6) System	10 Sep 2020 16:54:38
	System	10 Sep 2020 16:54:38

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:54:23', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ec9bef7c-fa98-4f2b-9364-0415d52af7f3'	(b) (4), (b) (6)	
	System	10 Sep 2020 16:54:38
User entered 'No (N)'	System	10 Sep 2020 16:54:38

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:54:30', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ec9bef7c-fa98-4f2b-9364-0415d52af7f3' User entered '10 Sep 2020 12:54'	(b) (4), (b) (6) System	10 Sep 2020 16:54:38
	System	10 Sep 2020 16:54:38

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '10 Sep 2020 12:40'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '10 Sep 2020 15:10'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:12:50', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd9a023ec-3de4-44f7-b40e-1c3ad65033a4' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Sep 2020 01:16:53
	System	11 Sep 2020 01:16:53

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:16:41', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd9a023ec-3de4-44f7-b40e-1c3ad65033a4' User entered '97.2'	(b) (4), (b) (6) System	11 Sep 2020 01:16:53
	System	11 Sep 2020 01:16:53

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:16:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd9a023ec-3de4-44f7-b40e-1c3ad65033a4' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 01:16:53
	System	11 Sep 2020 01:16:53

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:16:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd9a023ec-3de4-44f7-b40e-1c3ad65033a4' User entered '10 Sep 2020 21:16'	(b) (4), (b) (6) System	11 Sep 2020 01:16:53
	System	11 Sep 2020 01:16:53

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '10 Sep 2020 16:05'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 2'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:26:20', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '983c0113-c123-4659-99f1-482e6726c3b7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:27:18', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '983c0113-c123-4659-99f1-482e6726c3b7' User entered '98.0'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:27:24', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '983c0113-c123-4659-99f1-482e6726c3b7' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:27:31', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '983c0113-c123-4659-99f1-482e6726c3b7' User entered '11 Sep 2020 22:27'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 3'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:31:24', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7be0872a-7a94-4a14-b059-88b961b3e6a7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	13 Sep 2020 01:31:40
	System	13 Sep 2020 01:31:40

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:31:30', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7be0872a-7a94-4a14-b059-88b961b3e6a7' User entered '97.4'	(b) (4), (b) (6) System	13 Sep 2020 01:31:40
	System	13 Sep 2020 01:31:40

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:31:34', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7be0872a-7a94-4a14-b059-88b961b3e6a7' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 01:31:40
	System	13 Sep 2020 01:31:40

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:31:38', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7be0872a-7a94-4a14-b059-88b961b3e6a7' User entered '12 Sep 2020 21:31'	(b) (4), (b) (6) System	13 Sep 2020 01:31:40
	System	13 Sep 2020 01:31:40

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 4'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:24:17', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0557cd8b-c903-4c73-aa27-bb5585281c41' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Sep 2020 03:24:51
	System	14 Sep 2020 03:24:51

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:24:41', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0557cd8b-c903-4c73-aa27-bb5585281c41' User entered '97.6'	(b) (4), (b) (6) System	14 Sep 2020 03:24:51
	System	14 Sep 2020 03:24:51

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:24:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0557cd8b-c903-4c73-aa27-bb5585281c41' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 03:24:51
	System	14 Sep 2020 03:24:51

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:24:49', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0557cd8b-c903-4c73-aa27-bb5585281c41' User entered '13 Sep 2020 23:24'	(b) (4), (b) (6) System	14 Sep 2020 03:24:51
	System	14 Sep 2020 03:24:51

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 5'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:17:17', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bb161b1-e505-4a36-9373-23e8d3ee2d13' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 03:20:44
	System	15 Sep 2020 03:20:44

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:20:34', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bb161b1-e505-4a36-9373-23e8d3ee2d13' User entered '97.0'	(b) (4), (b) (6) System	15 Sep 2020 03:20:44
	System	15 Sep 2020 03:20:44

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:20:38', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bb161b1-e505-4a36-9373-23e8d3ee2d13'	(b) (4), (b) (6)	
User entered 'No (N)'	System	15 Sep 2020 03:20:44

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:20:42', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bb161b1-e505-4a36-9373-23e8d3ee2d13' User entered '14 Sep 2020 23:20'	(b) (4), (b) (6) System	15 Sep 2020 03:20:44
	System	15 Sep 2020 03:20:44

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 6'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:40:16', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b36758f7-a1ac-4982-9101-04cf242d24d7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Sep 2020 02:40:54
	System	16 Sep 2020 02:40:54

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:40:38', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b36758f7-a1ac-4982-9101-04cf242d24d7' User entered '97.4'	(b) (4), (b) (6) System	16 Sep 2020 02:40:54
	System	16 Sep 2020 02:40:54

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:40:47', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b36758f7-a1ac-4982-9101-04cf242d24d7' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 02:40:54
	System	16 Sep 2020 02:40:54

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:40:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b36758f7-a1ac-4982-9101-04cf242d24d7' User entered '15 Sep 2020 22:40'	(b) (4), (b) (6) System	16 Sep 2020 02:40:54
	System	16 Sep 2020 02:40:54

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 7'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:12', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c381fe7f-cca1-443a-beb9-ad033bcad970'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	17 Sep 2020 07:05:26

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:18', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c381fe7f-cca1-443a-beb9-ad033bcad970' User entered '97.8'	(b) (4), (b) (6) System	17 Sep 2020 07:05:26
	System	17 Sep 2020 07:05:26

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:21', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c381fe7f-cca1-443a-beb9-ad033bcad970' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 07:05:26
	System	17 Sep 2020 07:05:26

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:25', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c381fe7f-cca1-443a-beb9-ad033bcad970' User entered '17 Sep 2020 03:05'	(b) (4), (b) (6) System	17 Sep 2020 07:05:26
	System	17 Sep 2020 07:05:26

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:54:59', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '356de52b-f138-4489-ab3d-856233d49c40'	(b) (4), (b) (6)	
User entered 'None (1)'	System	10 Sep 2020 16:55:20

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:55:03', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '356de52b-f138-4489-ab3d-856233d49c40' User entered 'No (N)'	(b) (4), (b) (6) System	10 Sep 2020 16:55:20
	System	10 Sep 2020 16:55:20

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:55:06', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '356de52b-f138-4489-ab3d-856233d49c40' User entered 'No (N)'	(b) (4), (b) (6) System	10 Sep 2020 16:55:20
	System	10 Sep 2020 16:55:20

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:55:11', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '356de52b-f138-4489-ab3d-856233d49c40'	(b) (4), (b) (6)	
User entered 'None (1)'	System	10 Sep 2020 16:55:20

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:55:16', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '356de52b-f138-4489-ab3d-856233d49c40' User entered '10 Sep 2020 12:55'	(b) (4), (b) (6) System	10 Sep 2020 16:55:20
	System	10 Sep 2020 16:55:20

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '10 Sep 2020 12:40'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '10 Sep 2020 15:10'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:09', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '63b092f5-babf-4a9c-b5c6-836744da5a40' User entered 'None (1)'	(b) (4), (b) (6) System	11 Sep 2020 01:17:35
	System	11 Sep 2020 01:17:35

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:14', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '63b092f5-babf-4a9c-b5c6-836744da5a40' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 01:17:35
	System	11 Sep 2020 01:17:35

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:22', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '63b092f5-babf-4a9c-b5c6-836744da5a40' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 01:17:35
	System	11 Sep 2020 01:17:35

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:30', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '63b092f5-babf-4a9c-b5c6-836744da5a40'	(b) (4), (b) (6)	
User entered 'None (1)'	System	11 Sep 2020 01:17:35

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:33', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '63b092f5-babf-4a9c-b5c6-836744da5a40' User entered '10 Sep 2020 21:17'	(b) (4), (b) (6) System	11 Sep 2020 01:17:35
	System	11 Sep 2020 01:17:35

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '10 Sep 2020 16:05'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
Data entry locked.	(b) (4), (b) (6)	
	System	10 Sep 2020 16:23:29
User entered 'Day 2'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:27:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '826492ad-52f4-49cd-8ba1-8b06e50cda84'	(b) (4), (b) (6)	
User entered 'None (1)'	System	12 Sep 2020 02:28:34

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:27:55', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '826492ad-52f4-49cd-8ba1-8b06e50cda84' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:34
	System	12 Sep 2020 02:28:34

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '826492ad-52f4-49cd-8ba1-8b06e50cda84' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:34
	System	12 Sep 2020 02:28:34

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:10', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '826492ad-52f4-49cd-8ba1-8b06e50cda84'	(b) (4), (b) (6)	12 Sep 2020 02:28:34
User entered 'None (1)'	System	12 Sep 2020 02:28:34

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:16', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '826492ad-52f4-49cd-8ba1-8b06e50cda84' User entered '11 Sep 2020 22:28'	(b) (4), (b) (6) System	12 Sep 2020 02:28:34
	System	12 Sep 2020 02:28:34

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 3'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:31:45', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ac1d6862-415e-4918-a64d-abb11cbcd4d2'	(b) (4), (b) (6)	
	System	13 Sep 2020 01:33:11
User entered 'None (1)'	System	13 Sep 2020 01:33:11

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:31:49', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ac1d6862-415e-4918-a64d-abb11cbcd4d2' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 01:33:11
	System	13 Sep 2020 01:33:11

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:31:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ac1d6862-415e-4918-a64d-abb11cbcd4d2'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	13 Sep 2020 01:33:11

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:32:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ac1d6862-415e-4918-a64d-abb11cbcd4d2' User entered '8'	(b) (4), (b) (6) System	13 Sep 2020 01:33:11
	System	13 Sep 2020 01:33:11

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:32:59', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ac1d6862-415e-4918-a64d-abb11cbcd4d2'	(b) (4), (b) (6) System	13 Sep 2020 01:33:11
User entered 'None (1)'	System	13 Sep 2020 01:33:11

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:33:09', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ac1d6862-415e-4918-a64d-abb11cbcd4d2'	(b) (4), (b) (6) System	13 Sep 2020 01:33:11
User entered '12 Sep 2020 21:33'	System	13 Sep 2020 01:33:11

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 4'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:09', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8315cae-e09a-4b61-bab1-79e3570d0515' User entered 'None (1)'	(b) (4), (b) (6) System	14 Sep 2020 03:23:38
	System	14 Sep 2020 03:23:38

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:12', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8315cae-e09a-4b61-bab1-79e3570d0515' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 03:23:38
	System	14 Sep 2020 03:23:38

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:18', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8315cae-e09a-4b61-bab1-79e3570d0515' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Sep 2020 03:23:38
	System	14 Sep 2020 03:23:38

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:26', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8315cae-e09a-4b61-bab1-79e3570d0515' User entered '4'	(b) (4), (b) (6) System	14 Sep 2020 03:23:38
	System	14 Sep 2020 03:23:38

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:31', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8315cae-e09a-4b61-bab1-79e3570d0515' User entered 'None (1)'	(b) (4), (b) (6) System	14 Sep 2020 03:23:38
	System	14 Sep 2020 03:23:38

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:37', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8315cae-e09a-4b61-bab1-79e3570d0515' User entered '13 Sep 2020 23:23'	(b) (4), (b) (6) System	14 Sep 2020 03:23:38
	System	14 Sep 2020 03:23:38

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 5'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:16:26', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '5cc64dac-4a04-412b-9b7d-c5d11c2032cb' User entered 'None (1)'	(b) (4), (b) (6) System	15 Sep 2020 03:16:45
	System	15 Sep 2020 03:16:45

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:16:30', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '5cc64dac-4a04-412b-9b7d-c5d11c2032cb' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 03:16:45
	System	15 Sep 2020 03:16:45

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:16:34', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '5cc64dac-4a04-412b-9b7d-c5d11c2032cb' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 03:16:45
	System	15 Sep 2020 03:16:45

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:16:38', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '5cc64dac-4a04-412b-9b7d-c5d11c2032cb' User entered 'None (1)'	(b) (4), (b) (6) System	15 Sep 2020 03:16:45
	System	15 Sep 2020 03:16:45

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:16:41', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '5cc64dac-4a04-412b-9b7d-c5d11c2032cb' User entered '14 Sep 2020 23:16'	(b) (4), (b) (6) System	15 Sep 2020 03:16:45
	System	15 Sep 2020 03:16:45

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 6'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:04', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8c9b3e1-9cf1-4bc0-9461-8b5afe5ce162'	(b) (4), (b) (6)	
	System	16 Sep 2020 02:39:26
User entered 'None (1)'	System	16 Sep 2020 02:39:26

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:07', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8c9b3e1-9cf1-4bc0-9461-8b5afe5ce162'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Sep 2020 02:39:26

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:12', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8c9b3e1-9cf1-4bc0-9461-8b5afe5ce162'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Sep 2020 02:39:26

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:16', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8c9b3e1-9cf1-4bc0-9461-8b5afe5ce162'	(b) (4), (b) (6)	
	System	16 Sep 2020 02:39:26
User entered 'None (1)'	System	16 Sep 2020 02:39:26

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:23', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e8c9b3e1-9cf1-4bc0-9461-8b5afe5ce162'	(b) (4), (b) (6) System	16 Sep 2020 02:39:26
User entered '15 Sep 2020 22:39'	System	16 Sep 2020 02:39:26

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 7'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:31', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '90b02ef8-f1a4-409c-abeb-a27185082f39'	(b) (4), (b) (6)	
	System	17 Sep 2020 07:05:52
User entered 'None (1)'	System	17 Sep 2020 07:05:52

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:36', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '90b02ef8-f1a4-409c-abeb-a27185082f39' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 07:05:52
	System	17 Sep 2020 07:05:52

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:42', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '90b02ef8-f1a4-409c-abeb-a27185082f39' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 07:05:52
	System	17 Sep 2020 07:05:52

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '90b02ef8-f1a4-409c-abeb-a27185082f39'	(b) (4), (b) (6)	
	System	17 Sep 2020 07:05:52
User entered 'None (1)'	System	17 Sep 2020 07:05:52

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:49', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '90b02ef8-f1a4-409c-abeb-a27185082f39' User entered '17 Sep 2020 03:05'	(b) (4), (b) (6) System	17 Sep 2020 07:05:52
	System	17 Sep 2020 07:05:52

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:56:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd7a9abfc-fd4b-4fb8-a9b0-6cb22b2a9944' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 16:56:34
	System	10 Sep 2020 16:56:34

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:56:04', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd7a9abfc-fd4b-4fb8-a9b0-6cb22b2a9944' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 16:56:34
	System	10 Sep 2020 16:56:34

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:56:08', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd7a9abfc-fd4b-4fb8-a9b0-6cb22b2a9944' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 16:56:34
	System	10 Sep 2020 16:56:34

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:56:11', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd7a9abfc-fd4b-4fb8-a9b0-6cb22b2a9944' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 16:56:34
	System	10 Sep 2020 16:56:34

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:56:14', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd7a9abfc-fd4b-4fb8-a9b0-6cb22b2a9944' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 16:56:34
	System	10 Sep 2020 16:56:34

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:56:17', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd7a9abfc-fd4b-4fb8-a9b0-6cb22b2a9944' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 16:56:34
	System	10 Sep 2020 16:56:34

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:56:24', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd7a9abfc-fd4b-4fb8-a9b0-6cb22b2a9944'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Sep 2020 16:56:34

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T12:56:28', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'd7a9abfc-fd4b-4fb8-a9b0-6cb22b2a9944'	(b) (4), (b) (6) System	10 Sep 2020 16:56:34
User entered '10 Sep 2020 12:56'	System	10 Sep 2020 16:56:34

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '10 Sep 2020 12:40'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '10 Sep 2020 15:10'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:39', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0ffa3139-a403-4b50-8815-e4f16145530b' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 01:18:07
	System	11 Sep 2020 01:18:07

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:42', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0ffa3139-a403-4b50-8815-e4f16145530b' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 01:18:07
	System	11 Sep 2020 01:18:07

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:45', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0ffa3139-a403-4b50-8815-e4f16145530b' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 01:18:07
	System	11 Sep 2020 01:18:07

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:49', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0ffa3139-a403-4b50-8815-e4f16145530b' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 01:18:07
	System	11 Sep 2020 01:18:07

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:52', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0ffa3139-a403-4b50-8815-e4f16145530b' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 01:18:07
	System	11 Sep 2020 01:18:07

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0ffa3139-a403-4b50-8815-e4f16145530b' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 01:18:07
	System	11 Sep 2020 01:18:07

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:17:59', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0ffa3139-a403-4b50-8815-e4f16145530b' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 01:18:07
	System	11 Sep 2020 01:18:07

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-10T21:18:03', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0ffa3139-a403-4b50-8815-e4f16145530b' User entered '10 Sep 2020 21:18'	(b) (4), (b) (6) System	11 Sep 2020 01:18:07
	System	11 Sep 2020 01:18:07

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '10 Sep 2020 16:05'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
Data entry locked.	(b) (4), (b) (6)	
	System	10 Sep 2020 16:23:29
User entered 'Day 2'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:24', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2229afeb-fedb-4042-965e-7730832991e2' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:28', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2229afeb-fedb-4042-965e-7730832991e2' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:32', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2229afeb-fedb-4042-965e-7730832991e2' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:35', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2229afeb-fedb-4042-965e-7730832991e2' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:38', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2229afeb-fedb-4042-965e-7730832991e2' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:40', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2229afeb-fedb-4042-965e-7730832991e2' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:47', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2229afeb-fedb-4042-965e-7730832991e2' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-11T22:28:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2229afeb-fedb-4042-965e-7730832991e2' User entered '11 Sep 2020 22:28'	(b) (4), (b) (6) System	12 Sep 2020 02:28:54
	System	12 Sep 2020 02:28:54

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 3'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:33:14', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b9567420-fa4f-4c13-aa8b-b8ade58fd8d1' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 01:33:53
	System	13 Sep 2020 01:33:53

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:33:19', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b9567420-fa4f-4c13-aa8b-b8ade58fd8d1' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 01:33:53
	System	13 Sep 2020 01:33:53

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:33:27', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b9567420-fa4f-4c13-aa8b-b8ade58fd8d1' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 01:33:53
	System	13 Sep 2020 01:33:53

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:33:29', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b9567420-fa4f-4c13-aa8b-b8ade58fd8d1' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 01:33:53
	System	13 Sep 2020 01:33:53

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:33:42', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b9567420-fa4f-4c13-aa8b-b8ade58fd8d1' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 01:33:53
	System	13 Sep 2020 01:33:53

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:33:44', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b9567420-fa4f-4c13-aa8b-b8ade58fd8d1' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 01:33:53
	System	13 Sep 2020 01:33:53

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:33:48', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b9567420-fa4f-4c13-aa8b-b8ade58fd8d1' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 01:33:53
	System	13 Sep 2020 01:33:53

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-12T21:33:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b9567420-fa4f-4c13-aa8b-b8ade58fd8d1' User entered '12 Sep 2020 21:33'	(b) (4), (b) (6) System	13 Sep 2020 01:33:53
	System	13 Sep 2020 01:33:53

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 4'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:43', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '22d521d3-07ed-43e9-b260-a8ebac65cff8' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 03:24:14
	System	14 Sep 2020 03:24:14

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:47', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '22d521d3-07ed-43e9-b260-a8ebac65cff8' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 03:24:14
	System	14 Sep 2020 03:24:14

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '22d521d3-07ed-43e9-b260-a8ebac65cff8' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 03:24:14
	System	14 Sep 2020 03:24:14

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '22d521d3-07ed-43e9-b260-a8ebac65cff8' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 03:24:14
	System	14 Sep 2020 03:24:14

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:23:57', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '22d521d3-07ed-43e9-b260-a8ebac65cff8' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 03:24:14
	System	14 Sep 2020 03:24:14

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:24:01', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '22d521d3-07ed-43e9-b260-a8ebac65cff8' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 03:24:14
	System	14 Sep 2020 03:24:14

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:24:05', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '22d521d3-07ed-43e9-b260-a8ebac65cff8' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 03:24:14
	System	14 Sep 2020 03:24:14

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-13T23:24:08', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '22d521d3-07ed-43e9-b260-a8ebac65cff8' User entered '13 Sep 2020 23:24'	(b) (4), (b) (6) System	14 Sep 2020 03:24:14
	System	14 Sep 2020 03:24:14

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
Data entry locked.	(b) (4), (b) (6)	
	System	10 Sep 2020 16:23:29
User entered 'Day 5'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:16:47', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fd192f8b-ab11-4fb7-aa31-389c82226a6a' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 03:17:10
	System	15 Sep 2020 03:17:10

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:16:50', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fd192f8b-ab11-4fb7-aa31-389c82226a6a' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 03:17:10
	System	15 Sep 2020 03:17:10

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:16:52', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fd192f8b-ab11-4fb7-aa31-389c82226a6a' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 03:17:10
	System	15 Sep 2020 03:17:10

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:16:55', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fd192f8b-ab11-4fb7-aa31-389c82226a6a' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 03:17:10
	System	15 Sep 2020 03:17:10

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:16:58', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fd192f8b-ab11-4fb7-aa31-389c82226a6a' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 03:17:10
	System	15 Sep 2020 03:17:10

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:17:01', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fd192f8b-ab11-4fb7-aa31-389c82226a6a' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 03:17:10
	System	15 Sep 2020 03:17:10

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:17:05', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fd192f8b-ab11-4fb7-aa31-389c82226a6a' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 03:17:10
	System	15 Sep 2020 03:17:10

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-14T23:17:08', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fd192f8b-ab11-4fb7-aa31-389c82226a6a' User entered '14 Sep 2020 23:17'	(b) (4), (b) (6) System	15 Sep 2020 03:17:10
	System	15 Sep 2020 03:17:10

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 6'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:29', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '75317e1b-7c69-4fde-80e4-1303ada9f02c' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 02:40:11
	System	16 Sep 2020 02:40:11

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:32', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '75317e1b-7c69-4fde-80e4-1303ada9f02c' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 02:40:11
	System	16 Sep 2020 02:40:11

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:40', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '75317e1b-7c69-4fde-80e4-1303ada9f02c' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 02:40:11
	System	16 Sep 2020 02:40:11

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:43', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '75317e1b-7c69-4fde-80e4-1303ada9f02c' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 02:40:11
	System	16 Sep 2020 02:40:11

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '75317e1b-7c69-4fde-80e4-1303ada9f02c' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 02:40:11
	System	16 Sep 2020 02:40:11

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:39:48', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '75317e1b-7c69-4fde-80e4-1303ada9f02c' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 02:40:11
	System	16 Sep 2020 02:40:11

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:40:04', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '75317e1b-7c69-4fde-80e4-1303ada9f02c' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 02:40:11
	System	16 Sep 2020 02:40:11

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-15T22:40:07', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '75317e1b-7c69-4fde-80e4-1303ada9f02c' User entered '15 Sep 2020 22:40'	(b) (4), (b) (6) System	16 Sep 2020 02:40:11
	System	16 Sep 2020 02:40:11

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 7'	System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bf3c1cd-4603-49d3-9184-0a79bec95d20' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 07:06:24
	System	17 Sep 2020 07:06:24

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:56', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bf3c1cd-4603-49d3-9184-0a79bec95d20' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 07:06:24
	System	17 Sep 2020 07:06:24

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:05:59', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bf3c1cd-4603-49d3-9184-0a79bec95d20' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 07:06:24
	System	17 Sep 2020 07:06:24

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:06:03', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bf3c1cd-4603-49d3-9184-0a79bec95d20' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 07:06:24
	System	17 Sep 2020 07:06:24

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:06:08', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bf3c1cd-4603-49d3-9184-0a79bec95d20' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 07:06:24
	System	17 Sep 2020 07:06:24

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:06:10', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bf3c1cd-4603-49d3-9184-0a79bec95d20' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 07:06:24
	System	17 Sep 2020 07:06:24

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:06:17', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bf3c1cd-4603-49d3-9184-0a79bec95d20' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 07:06:24
	System	17 Sep 2020 07:06:24

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-09-17T03:06:19', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '7bf3c1cd-4603-49d3-9184-0a79bec95d20' User entered '17 Sep 2020 03:06'	(b) (4), (b) (6) System	17 Sep 2020 07:06:24
	System	17 Sep 2020 07:06:24

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:48
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 16:23:29

US3242314

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Yes (Y)'	Grace Newville (b) (4)	18 Sep 2020 21:58:25
	(b) (4)	

US3242314

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered '18 Sep 2020'	Grace Newville (b) (4)	18 Sep 2020 21:58:25
	(b) (4)	

US3242314

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	18 Sep 2020 21:58:25
	(b) (4)	

US3242314

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:56
User entered empty.	Grace Newville (b) (4)	18 Sep 2020 21:58:25
	(b) (4)	

US3242314

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Grace Newville (b) (4)	18 Sep 2020 21:58:28
	(b) (4)	

US3242314

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'I'	(b) (4), (b) (6) System	18 Sep 2020 21:58:28

US3242314

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:06:04

US3242314

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:06:04

US3242314

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 17:06:04

US3242314

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:06:04

US3242314

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:06:08

US3242314

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:47:37
User entered 'I'	(b) (4), (b) (6) System	25 Sep 2020 17:06:08

US3242314

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	01 Oct 2020 19:47:50
	(b) (4)	

US3242314

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '1 Oct 2020'	Erynn McKinley (b) (4)	01 Oct 2020 19:47:50
	(b) (4)	

US3242314

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	01 Oct 2020 19:47:50
	(b) (4)	

US3242314

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Erynn McKinley (b) (4)	01 Oct 2020 19:47:50
	(b) (4)	

US3242314

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	01 Oct 2020 19:47:53
	(b) (4)	

US3242314

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:40
User entered 'I'	(b) (4), (b) (6) System	01 Oct 2020 19:47:53

US3242314

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 12:40:37
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '9 Oct 2020'	Erynn McKinley (b) (4)	09 Oct 2020 12:40:37
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	09 Oct 2020 12:40:37
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'VISIT2'	(b) (4), (b) (6) System	09 Oct 2020 12:40:37

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	13 Apr 2021 13:04:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:12:48
User closed query 'Please enter day of date as dd (i.e 09)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:12:35
Query 'Please enter day of date as dd (i.e 09)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	08 Apr 2021 12:33:16
Signature has been broken.	Donna Toepfer (b) (4)	08 Apr 2021 12:32:56
User entered '09 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Apr 2021 12:32:56
User opened query 'Please enter day of date as dd (i.e 09)' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:52:20
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:51:52
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '9 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:51:38
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Un-verified.	Erynn McKinley (b) (4)	22 Dec 2020 17:34:03
	(b) (4)	
User entered '08:05' reason for change: Data Entry Error	Erynn McKinley (b) (4)	22 Dec 2020 17:34:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '8:05'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User entered '09 Oct 2020 08:05'	System	08 Apr 2021 12:32:56
User entered '9 Oct 2020 08:05'	System	22 Dec 2020 17:34:03
User entered '9 Oct 2020 8:05'	System	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '97.1' F	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered empty.	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '68'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'bpm'	(b) (4), (b) (6) System	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '16'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '128'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '80'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User signature succeeded.	(b) (4), (b) (6)	
	Jon Finley (b) (4)	13 Apr 2021 13:04:11
User closed query 'Please enter day of date as dd (i.e. 09)' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 00:14:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:12:48
Query 'Please enter day of date as dd (i.e. 09)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	08 Apr 2021 12:34:27
Signature has been broken.	Donna Toepfer (b) (4)	08 Apr 2021 12:34:12
User entered '09 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Apr 2021 12:34:12
User opened query 'Please enter day of date as dd (i.e. 09)' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:53:31
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:52:56
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '9 Oct 2020'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:51:38
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Un-verified.	Erynn McKinley (b) (4)	22 Dec 2020 17:34:03
	(b) (4)	
User entered '09:32' reason for change: Data Entry Error	Erynn McKinley (b) (4)	22 Dec 2020 17:34:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '9:32'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User entered '09 Oct 2020 09:32'	System	08 Apr 2021 12:34:12
User entered '9 Oct 2020 09:32'	System	22 Dec 2020 17:34:03
User entered '9 Oct 2020 9:32'	System	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '97.9' F	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered empty.	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '68'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'bpm'	(b) (4), (b) (6) System	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '16'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '128'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '82'	Erynn McKinley (b) (4)	09 Oct 2020 19:46:11
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 19:46:11

US3242314

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'No (N)'	Erynn McKinley (b) (4)	09 Oct 2020 12:40:44
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered empty.	Erynn McKinley (b) (4)	09 Oct 2020 12:40:44
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 13:03:19
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered empty.	Erynn McKinley (b) (4)	09 Oct 2020 13:03:19
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered empty.	Erynn McKinley (b) (4)	09 Oct 2020 13:03:19
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:04:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:11:18
	(b) (4), (b) (6)	
User closed query 'Please enter day of date as dd (i.e. 09)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:10:50
	(b) (4), (b) (6)	
Query 'Please enter day of date as dd (i.e. 09)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	08 Apr 2021 12:30:32
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
Signature has been broken.	Donna Toepfer (b) (4)	08 Apr 2021 12:30:06
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '09 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Apr 2021 12:30:06
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User opened query 'Please enter day of date as dd (i.e. 09)' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:50:44
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:50:20
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
	(b) (4), (b) (6)	
User entered '9 Oct 2020'	Erynn McKinley (b) (4)	09 Oct 2020 13:03:19
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:50:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Un-verified.	Erynn McKinley (b) (4)	22 Dec 2020 17:34:45
	(b) (4)	
User entered '09:01' reason for change: Data Entry Error	Erynn McKinley (b) (4)	22 Dec 2020 17:34:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '9:01'	Erynn McKinley (b) (4)	09 Oct 2020 13:03:19
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User entered '09 Oct 2020 09:01'	System	08 Apr 2021 12:30:06
User entered '9 Oct 2020 09:01'	System	22 Dec 2020 17:34:45
User entered '9 Oct 2020 9:01'	System	09 Oct 2020 13:03:19

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Left Arm (LEFT ARM)'	Erynn McKinley (b) (4)	09 Oct 2020 13:03:19
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'ONCE'	System	09 Oct 2020 13:03:19

US3242314

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:28

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 12:41:14
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '9 Oct 2020'	Erynn McKinley (b) (4)	09 Oct 2020 12:41:14
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:51:09
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Un-verified.	Erynn McKinley (b) (4)	22 Dec 2020 17:35:00
	(b) (4)	
User entered '08:32' reason for change: Data Entry Error	Erynn McKinley (b) (4)	22 Dec 2020 17:35:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '8:32'	Erynn McKinley (b) (4)	09 Oct 2020 12:41:14
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered '9 Oct 2020 08:32'	(b) (4), (b) (6)	
	System	22 Dec 2020 17:35:00
User entered '9 Oct 2020 8:32'	System	09 Oct 2020 12:41:14

US3242314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:14:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:04:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:10:09
	(b) (4), (b) (6)	
User closed query 'Please enter day of date as dd (i.e. 09).' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:09:41
	(b) (4), (b) (6)	
Query 'Please enter day of date as dd (i.e. 09).' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	08 Apr 2021 18:04:14
	(b) (4), (b) (6)	
Signature has been broken.	Donna Toepfer (b) (4)	08 Apr 2021 18:03:35
	(b) (4), (b) (6)	
User entered '09 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Apr 2021 18:03:35
	(b) (4), (b) (6)	
User opened query 'Please enter day of date as dd (i.e. 09).' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:49:15
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 19:48:49
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
	(b) (4), (b) (6)	
User entered '9 Oct 2020'	Erynn McKinley (b) (4)	09 Oct 2020 12:41:42
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	09 Oct 2020 12:41:42

US3242314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 12:41:42
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:48:43
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Un-verified.	Erynn McKinley (b) (4)	22 Dec 2020 17:35:17
	(b) (4)	
User entered '08:25' reason for change: Data Entry Error	Erynn McKinley (b) (4)	22 Dec 2020 17:35:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '8:25'	Erynn McKinley (b) (4)	09 Oct 2020 12:41:42
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User entered '09 Oct 2020 08:25'	System	08 Apr 2021 18:03:35
User entered '9 Oct 2020 08:25'	System	22 Dec 2020 17:35:17
User entered '9 Oct 2020 8:25'	System	09 Oct 2020 12:41:42

US3242314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erynn McKinley (b) (4)	09 Oct 2020 12:41:42

US3242314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'No (N)'	Erynn McKinley (b) (4)	09 Oct 2020 12:41:42
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered empty.	Erynn McKinley (b) (4)	09 Oct 2020 12:41:42
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered empty.	(b) (4), (b) (6) System	09 Oct 2020 12:41:42

US3242314

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 12:41:46
	(b) (4)	

US3242314

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered '1'	(b) (4), (b) (6) System	09 Oct 2020 12:41:46

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:29:26', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '1550e4db-bad0-4bfd-be3e-12022a6964c7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	09 Oct 2020 13:29:45
	System	09 Oct 2020 13:29:45

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:29:33', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '1550e4db-bad0-4bfd-be3e-12022a6964c7' User entered '97.9'	(b) (4), (b) (6) System	09 Oct 2020 13:29:45
	System	09 Oct 2020 13:29:45

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:29:37', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '1550e4db-bad0-4bfd-be3e-12022a6964c7' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 13:29:45
	System	09 Oct 2020 13:29:45

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:29:42', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '1550e4db-bad0-4bfd-be3e-12022a6964c7' User entered '09 Oct 2020 09:29'	(b) (4), (b) (6) System	09 Oct 2020 13:29:45
	System	09 Oct 2020 13:29:45

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '09 Oct 2020 09:21'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '09 Oct 2020 11:51'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:22:18', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8785aaf5-77f9-4785-bbec-748554219490' User entered 'Yes (Y)'	(b) (4), (b) (6) System	10 Oct 2020 01:22:38
	System	10 Oct 2020 01:22:38

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:22:25', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8785aaf5-77f9-4785-bbec-748554219490' User entered '97.8'	(b) (4), (b) (6) System	10 Oct 2020 01:22:38
	System	10 Oct 2020 01:22:38

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:22:30', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8785aaf5-77f9-4785-bbec-748554219490' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 01:22:38
	System	10 Oct 2020 01:22:38

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:22:34', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8785aaf5-77f9-4785-bbec-748554219490' User entered '09 Oct 2020 21:22'	(b) (4), (b) (6) System	10 Oct 2020 01:22:38
	System	10 Oct 2020 01:22:38

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '09 Oct 2020 12:46'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 2'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:05:48', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '50499157-9599-467f-90b4-da74ebb84dc3' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Oct 2020 02:07:03
	System	11 Oct 2020 02:07:03

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:06:25', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '50499157-9599-467f-90b4-da74ebb84dc3' User entered '98.6'	(b) (4), (b) (6) System	11 Oct 2020 02:07:03
	System	11 Oct 2020 02:07:03

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:06:39', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '50499157-9599-467f-90b4-da74ebb84dc3' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Oct 2020 02:07:03
	System	11 Oct 2020 02:07:03

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
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 'Subject was contacted and conmed recorded.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Nov 2020 06:49:26
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).	Grace Newville (b) (4) (b) (4)	14 Oct 2020 13:19:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:06:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '50499157-9599-467f-90b4-da74ebb84dc3'	System	11 Oct 2020 02:07:03
User entered '1'	System	11 Oct 2020 02:07:03

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:06:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '50499157-9599-467f-90b4-da74ebb84dc3' User entered '0'	(b) (4), (b) (6) System	11 Oct 2020 02:07:03
	System	11 Oct 2020 02:07:03

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:06:59', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '50499157-9599-467f-90b4-da74ebb84dc3' User entered '10 Oct 2020 21:06'	(b) (4), (b) (6) System	11 Oct 2020 02:07:03
	System	11 Oct 2020 02:07:03

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 3'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:01:26', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '9a7d5399-f72b-4a8d-9db6-79c9200d0492'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Oct 2020 05:02:11

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '9a7d5399-f72b-4a8d-9db6-79c9200d0492' User entered '96.9'	(b) (4), (b) (6) System	12 Oct 2020 05:02:11
	System	12 Oct 2020 05:02:11

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:05', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '9a7d5399-f72b-4a8d-9db6-79c9200d0492'	(b) (4), (b) (6)	
	System	12 Oct 2020 05:02:11
User entered 'No (N)'	System	12 Oct 2020 05:02:11

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:08', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '9a7d5399-f72b-4a8d-9db6-79c9200d0492'	(b) (4), (b) (6) System	12 Oct 2020 05:02:11
User entered '12 Oct 2020 00:02'	System	12 Oct 2020 05:02:11

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 4'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:45:45', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e99e79d0-83d6-4119-9b5a-13365cd68038' User entered 'Yes (Y)'	(b) (4), (b) (6) System	13 Oct 2020 03:47:01
	System	13 Oct 2020 03:47:01

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:46:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e99e79d0-83d6-4119-9b5a-13365cd68038' User entered '96.4'	(b) (4), (b) (6) System	13 Oct 2020 03:47:01
	System	13 Oct 2020 03:47:01

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:46:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e99e79d0-83d6-4119-9b5a-13365cd68038' User entered 'No (N)'	(b) (4), (b) (6) System	13 Oct 2020 03:47:01
	System	13 Oct 2020 03:47:01

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:46:58', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e99e79d0-83d6-4119-9b5a-13365cd68038' User entered '12 Oct 2020 22:46'	(b) (4), (b) (6) System	13 Oct 2020 03:47:01
	System	13 Oct 2020 03:47:01

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 5'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:49:12', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ee5a73ed-56a3-45fb-adbb-737727f76a61' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Oct 2020 02:50:25
	System	14 Oct 2020 02:50:25

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:15', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ee5a73ed-56a3-45fb-adbb-737727f76a61' User entered '97.5'	(b) (4), (b) (6) System	14 Oct 2020 02:50:25
	System	14 Oct 2020 02:50:25

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:19', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ee5a73ed-56a3-45fb-adbb-737727f76a61' User entered 'No (N)'	(b) (4), (b) (6) System	14 Oct 2020 02:50:25
	System	14 Oct 2020 02:50:25

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:21', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ee5a73ed-56a3-45fb-adbb-737727f76a61' User entered '13 Oct 2020 21:50'	(b) (4), (b) (6) System	14 Oct 2020 02:50:25
	System	14 Oct 2020 02:50:25

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 6'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:57:38', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '15409231-4f0d-40c7-887b-ec5b31469fc3'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	15 Oct 2020 10:57:56

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:57:47', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '15409231-4f0d-40c7-887b-ec5b31469fc3' User entered '97.8'	(b) (4), (b) (6) System	15 Oct 2020 10:57:56
	System	15 Oct 2020 10:57:56

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:57:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '15409231-4f0d-40c7-887b-ec5b31469fc3'	(b) (4), (b) (6)	
User entered 'No (N)'	System	15 Oct 2020 10:57:56

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:57:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '15409231-4f0d-40c7-887b-ec5b31469fc3' User entered '15 Oct 2020 05:57'	(b) (4), (b) (6) System	15 Oct 2020 10:57:56
	System	15 Oct 2020 10:57:56

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 7'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:40:58', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '05db06b6-7595-4c46-a1d1-02865316f290' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Oct 2020 02:41:18
	System	16 Oct 2020 02:41:18

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:03', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '05db06b6-7595-4c46-a1d1-02865316f290' User entered '97.7'	(b) (4), (b) (6) System	16 Oct 2020 02:41:18
	System	16 Oct 2020 02:41:18

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:08', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '05db06b6-7595-4c46-a1d1-02865316f290' User entered 'No (N)'	(b) (4), (b) (6) System	16 Oct 2020 02:41:18
	System	16 Oct 2020 02:41:18

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:13', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '05db06b6-7595-4c46-a1d1-02865316f290' User entered '15 Oct 2020 21:41'	(b) (4), (b) (6) System	16 Oct 2020 02:41:18
	System	16 Oct 2020 02:41:18

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:29:48', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '70a05127-5ab4-49bb-b5e0-69ef7e3a6e88'	(b) (4), (b) (6)	
	System	09 Oct 2020 13:30:23
User entered 'None (1)'	System	09 Oct 2020 13:30:23

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:05', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '70a05127-5ab4-49bb-b5e0-69ef7e3a6e88' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 13:30:23
	System	09 Oct 2020 13:30:23

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:10', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '70a05127-5ab4-49bb-b5e0-69ef7e3a6e88' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 13:30:23
	System	09 Oct 2020 13:30:23

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:15', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '70a05127-5ab4-49bb-b5e0-69ef7e3a6e88'	(b) (4), (b) (6)	
	System	09 Oct 2020 13:30:23
User entered 'None (1)'	System	09 Oct 2020 13:30:23

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:18', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '70a05127-5ab4-49bb-b5e0-69ef7e3a6e88' User entered '09 Oct 2020 09:30'	(b) (4), (b) (6) System	09 Oct 2020 13:30:23
	System	09 Oct 2020 13:30:23

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '09 Oct 2020 09:21'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '09 Oct 2020 11:51'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:22:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f93cf20c-69e3-4d59-997a-4432c13096e4'	(b) (4), (b) (6)	
	System	10 Oct 2020 01:23:08
User entered 'Does not interfere with activity (2)'	System	10 Oct 2020 01:23:08

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:22:50', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f93cf20c-69e3-4d59-997a-4432c13096e4' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 01:23:08
	System	10 Oct 2020 01:23:08

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:22:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f93cf20c-69e3-4d59-997a-4432c13096e4' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 01:23:08
	System	10 Oct 2020 01:23:08

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:23:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f93cf20c-69e3-4d59-997a-4432c13096e4' User entered 'None (1)'	(b) (4), (b) (6) System	10 Oct 2020 01:23:08
	System	10 Oct 2020 01:23:08

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:23:06', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f93cf20c-69e3-4d59-997a-4432c13096e4' User entered '09 Oct 2020 21:23'	(b) (4), (b) (6) System	10 Oct 2020 01:23:08
	System	10 Oct 2020 01:23:08

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '09 Oct 2020 12:46'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 2'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:07:13', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ce52e4ac-83e2-4d43-9b1d-5f6b833e6fa4'	(b) (4), (b) (6)	
	System	11 Oct 2020 02:07:49
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 02:07:49

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:07:20', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ce52e4ac-83e2-4d43-9b1d-5f6b833e6fa4'	(b) (4), (b) (6) System	11 Oct 2020 02:07:49
User entered 'No (N)'	System	11 Oct 2020 02:07:49

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:07:36', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ce52e4ac-83e2-4d43-9b1d-5f6b833e6fa4'	(b) (4), (b) (6) System	11 Oct 2020 02:07:49
User entered 'No (N)'	System	11 Oct 2020 02:07:49

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:07:41', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ce52e4ac-83e2-4d43-9b1d-5f6b833e6fa4'	(b) (4), (b) (6)	
	System	11 Oct 2020 02:07:49
User entered 'None (1)'	System	11 Oct 2020 02:07:49

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:07:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ce52e4ac-83e2-4d43-9b1d-5f6b833e6fa4'	(b) (4), (b) (6) System	11 Oct 2020 02:07:49
User entered '10 Oct 2020 21:07'	System	11 Oct 2020 02:07:49

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 3'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:20', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c75972ea-29a2-4b54-8f19-bc8ad45d0daf'	(b) (4), (b) (6) System	12 Oct 2020 05:02:37
User entered 'Does not interfere with activity (2)'	System	12 Oct 2020 05:02:37

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:23', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c75972ea-29a2-4b54-8f19-bc8ad45d0daf'	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Oct 2020 05:02:37

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:26', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c75972ea-29a2-4b54-8f19-bc8ad45d0daf' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 05:02:37
	System	12 Oct 2020 05:02:37

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:30', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c75972ea-29a2-4b54-8f19-bc8ad45d0daf'	(b) (4), (b) (6)	
User entered 'None (1)'	System	12 Oct 2020 05:02:37

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:33', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c75972ea-29a2-4b54-8f19-bc8ad45d0daf' User entered '12 Oct 2020 00:02'	(b) (4), (b) (6) System	12 Oct 2020 05:02:37
	System	12 Oct 2020 05:02:37

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 4'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:06', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e022ed7f-1e95-413a-a95f-9a0de7f88e61' User entered 'None (1)'	(b) (4), (b) (6) System	13 Oct 2020 03:47:29
	System	13 Oct 2020 03:47:29

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:10', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e022ed7f-1e95-413a-a95f-9a0de7f88e61' User entered 'No (N)'	(b) (4), (b) (6) System	13 Oct 2020 03:47:29
	System	13 Oct 2020 03:47:29

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:15', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e022ed7f-1e95-413a-a95f-9a0de7f88e61' User entered 'No (N)'	(b) (4), (b) (6) System	13 Oct 2020 03:47:29
	System	13 Oct 2020 03:47:29

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:18', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e022ed7f-1e95-413a-a95f-9a0de7f88e61' User entered 'None (1)'	(b) (4), (b) (6) System	13 Oct 2020 03:47:29
	System	13 Oct 2020 03:47:29

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:25', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e022ed7f-1e95-413a-a95f-9a0de7f88e61' User entered '12 Oct 2020 22:47'	(b) (4), (b) (6) System	13 Oct 2020 03:47:29
	System	13 Oct 2020 03:47:29

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 5'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:25', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'eb9e0f33-40fd-49b6-b5ac-6ac759fcd8d0'	(b) (4), (b) (6)	
User entered 'None (1)'	System	14 Oct 2020 02:50:40

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:29', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'eb9e0f33-40fd-49b6-b5ac-6ac759fcd8d0' User entered 'No (N)'	(b) (4), (b) (6) System	14 Oct 2020 02:50:40
	System	14 Oct 2020 02:50:40

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:31', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'eb9e0f33-40fd-49b6-b5ac-6ac759fcd8d0' User entered 'No (N)'	(b) (4), (b) (6) System	14 Oct 2020 02:50:40
	System	14 Oct 2020 02:50:40

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:34', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'eb9e0f33-40fd-49b6-b5ac-6ac759fcd8d0'	(b) (4), (b) (6)	
	System	14 Oct 2020 02:50:40
User entered 'None (1)'	System	14 Oct 2020 02:50:40

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:37', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'eb9e0f33-40fd-49b6-b5ac-6ac759fcd8d0' User entered '13 Oct 2020 21:50'	(b) (4), (b) (6) System	14 Oct 2020 02:50:40
	System	14 Oct 2020 02:50:40

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 6'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:57:58', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e14dc0-53e0-4380-8192-f86457a1fc47'	(b) (4), (b) (6)	
	System	15 Oct 2020 10:58:26
User entered 'None (1)'	System	15 Oct 2020 10:58:26

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:02', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e14dc0-53e0-4380-8192-f86457a1fc47'	(b) (4), (b) (6)	
User entered 'No (N)'	System	15 Oct 2020 10:58:26

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:08', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e14dc0-53e0-4380-8192-f86457a1fc47'	(b) (4), (b) (6)	
User entered 'No (N)'	System	15 Oct 2020 10:58:26

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:12', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e14dc0-53e0-4380-8192-f86457a1fc47'	(b) (4), (b) (6)	
	System	15 Oct 2020 10:58:26
User entered 'None (1)'	System	15 Oct 2020 10:58:26

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:22', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e14dc0-53e0-4380-8192-f86457a1fc47' User entered '15 Oct 2020 05:58'	(b) (4), (b) (6) System	15 Oct 2020 10:58:26
	System	15 Oct 2020 10:58:26

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 7'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:19', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '280d0d93-51c0-43d7-8aee-da71efe4f366'	(b) (4), (b) (6)	
User entered 'None (1)'	System	16 Oct 2020 02:41:35

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:22', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '280d0d93-51c0-43d7-8aee-da71efe4f366'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 02:41:35

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:25', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '280d0d93-51c0-43d7-8aee-da71efe4f366'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 02:41:35

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:28', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '280d0d93-51c0-43d7-8aee-da71efe4f366'	(b) (4), (b) (6)	16 Oct 2020 02:41:35
User entered 'None (1)'	System	16 Oct 2020 02:41:35

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:31', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '280d0d93-51c0-43d7-8aee-da71efe4f366' User entered '15 Oct 2020 21:41'	(b) (4), (b) (6) System	16 Oct 2020 02:41:35
	System	16 Oct 2020 02:41:35

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:22', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f043dd60-0946-4f5b-ae9-e4ae898e1e06' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 13:30:50
	System	09 Oct 2020 13:30:50

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:25', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f043dd60-0946-4f5b-ae9-e4ae898e1e06' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 13:30:50
	System	09 Oct 2020 13:30:50

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:27', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f043dd60-0946-4f5b-ae9-e4ae898e1e06' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 13:30:50
	System	09 Oct 2020 13:30:50

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:31', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f043dd60-0946-4f5b-ae9-e4ae898e1e06' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 13:30:50
	System	09 Oct 2020 13:30:50

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:33', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f043dd60-0946-4f5b-ae9-e4ae898e1e06' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 13:30:50
	System	09 Oct 2020 13:30:50

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:36', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f043dd60-0946-4f5b-ae9-e4ae898e1e06' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 13:30:50
	System	09 Oct 2020 13:30:50

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:40', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f043dd60-0946-4f5b-ae9-e4ae898e1e06' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 13:30:50
	System	09 Oct 2020 13:30:50

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T09:30:45', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f043dd60-0946-4f5b-ae9-e4ae898e1e06' User entered '09 Oct 2020 09:30'	(b) (4), (b) (6) System	09 Oct 2020 13:30:50
	System	09 Oct 2020 13:30:50

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '09 Oct 2020 09:21'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '09 Oct 2020 11:51'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:23:16', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f56da4a4-1613-4c37-a320-247921416076' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:23:38
	System	10 Oct 2020 01:23:38

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:23:18', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f56da4a4-1613-4c37-a320-247921416076' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:23:38
	System	10 Oct 2020 01:23:38

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:23:22', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f56da4a4-1613-4c37-a320-247921416076' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:23:38
	System	10 Oct 2020 01:23:38

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:23:24', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f56da4a4-1613-4c37-a320-247921416076' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:23:38
	System	10 Oct 2020 01:23:38

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:23:27', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f56da4a4-1613-4c37-a320-247921416076' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:23:38
	System	10 Oct 2020 01:23:38

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:23:29', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f56da4a4-1613-4c37-a320-247921416076' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 01:23:38
	System	10 Oct 2020 01:23:38

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:23:33', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f56da4a4-1613-4c37-a320-247921416076' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 01:23:38
	System	10 Oct 2020 01:23:38

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-09T21:23:36', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f56da4a4-1613-4c37-a320-247921416076' User entered '09 Oct 2020 21:23'	(b) (4), (b) (6) System	10 Oct 2020 01:23:38
	System	10 Oct 2020 01:23:38

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '09 Oct 2020 12:46'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 2'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:08:19', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afaeec8a-b1b5-45c6-a586-236ee64dc41f' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 02:09:29
	System	11 Oct 2020 02:09:29

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:08:26', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afaeec8a-b1b5-45c6-a586-236ee64dc41f' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 02:09:29
	System	11 Oct 2020 02:09:29

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:08:34', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afaec8a-b1b5-45c6-a586-236ee64dc41f' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	11 Oct 2020 02:09:29
	System	11 Oct 2020 02:09:29

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:08:42', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afaec8a-b1b5-45c6-a586-236ee64dc41f' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	11 Oct 2020 02:09:29
	System	11 Oct 2020 02:09:29

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:08:48', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afaeec8a-b1b5-45c6-a586-236ee64dc41f' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 02:09:29
	System	11 Oct 2020 02:09:29

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:09:10', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afaec8a-b1b5-45c6-a586-236ee64dc41f'	(b) (4), (b) (6)	
	System	11 Oct 2020 02:09:29
User entered 'Some interference with activity not requiring medical attention (2)'	System	11 Oct 2020 02:09:29

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:09:22', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afaec8a-b1b5-45c6-a586-236ee64dc41f' User entered 'No (N)'	(b) (4), (b) (6) System	11 Oct 2020 02:09:29
	System	11 Oct 2020 02:09:29

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-10T21:09:27', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afaeec8a-b1b5-45c6-a586-236ee64dc41f' User entered '10 Oct 2020 21:09'	(b) (4), (b) (6) System	11 Oct 2020 02:09:29
	System	11 Oct 2020 02:09:29

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 3'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:37', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '321ed6e3-92e7-4831-bb5d-50f220deb05f' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 05:02:59
	System	12 Oct 2020 05:02:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:41', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '321ed6e3-92e7-4831-bb5d-50f220deb05f' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 05:02:59
	System	12 Oct 2020 05:02:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:43', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '321ed6e3-92e7-4831-bb5d-50f220deb05f' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 05:02:59
	System	12 Oct 2020 05:02:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '321ed6e3-92e7-4831-bb5d-50f220deb05f' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 05:02:59
	System	12 Oct 2020 05:02:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:48', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '321ed6e3-92e7-4831-bb5d-50f220deb05f' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 05:02:59
	System	12 Oct 2020 05:02:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '321ed6e3-92e7-4831-bb5d-50f220deb05f' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 05:02:59
	System	12 Oct 2020 05:02:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '321ed6e3-92e7-4831-bb5d-50f220deb05f' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 05:02:59
	System	12 Oct 2020 05:02:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T00:02:58', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '321ed6e3-92e7-4831-bb5d-50f220deb05f' User entered '12 Oct 2020 00:02'	(b) (4), (b) (6) System	12 Oct 2020 05:02:59
	System	12 Oct 2020 05:02:59

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 4'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:34', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f9f1e9a8-7fd3-4f4c-a64c-4931b490b883' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 03:48:06
	System	13 Oct 2020 03:48:06

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:37', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f9f1e9a8-7fd3-4f4c-a64c-4931b490b883' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 03:48:06
	System	13 Oct 2020 03:48:06

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:40', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f9f1e9a8-7fd3-4f4c-a64c-4931b490b883' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 03:48:06
	System	13 Oct 2020 03:48:06

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:47', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f9f1e9a8-7fd3-4f4c-a64c-4931b490b883' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 03:48:06
	System	13 Oct 2020 03:48:06

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:50', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f9f1e9a8-7fd3-4f4c-a64c-4931b490b883' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 03:48:06
	System	13 Oct 2020 03:48:06

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:53', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f9f1e9a8-7fd3-4f4c-a64c-4931b490b883' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 03:48:06
	System	13 Oct 2020 03:48:06

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:47:58', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f9f1e9a8-7fd3-4f4c-a64c-4931b490b883' User entered 'No (N)'	(b) (4), (b) (6) System	13 Oct 2020 03:48:06
	System	13 Oct 2020 03:48:06

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-12T22:48:01', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'f9f1e9a8-7fd3-4f4c-a64c-4931b490b883' User entered '12 Oct 2020 22:48'	(b) (4), (b) (6) System	13 Oct 2020 03:48:06
	System	13 Oct 2020 03:48:06

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 5'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:42', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c852ef53-82fb-4cd1-b911-962ef368e935' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 02:51:08
	System	14 Oct 2020 02:51:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:45', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c852ef53-82fb-4cd1-b911-962ef368e935' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 02:51:08
	System	14 Oct 2020 02:51:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:47', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c852ef53-82fb-4cd1-b911-962ef368e935' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 02:51:08
	System	14 Oct 2020 02:51:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:50', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c852ef53-82fb-4cd1-b911-962ef368e935' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 02:51:08
	System	14 Oct 2020 02:51:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:52', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c852ef53-82fb-4cd1-b911-962ef368e935' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 02:51:08
	System	14 Oct 2020 02:51:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:50:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c852ef53-82fb-4cd1-b911-962ef368e935' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 02:51:08
	System	14 Oct 2020 02:51:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:51:01', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c852ef53-82fb-4cd1-b911-962ef368e935'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Oct 2020 02:51:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-13T21:51:04', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'c852ef53-82fb-4cd1-b911-962ef368e935' User entered '13 Oct 2020 21:51'	(b) (4), (b) (6) System	14 Oct 2020 02:51:08
	System	14 Oct 2020 02:51:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 6'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:26', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8411c480-58de-4804-81d6-e73ab9c101da' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 10:58:48
	System	15 Oct 2020 10:58:48

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:29', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8411c480-58de-4804-81d6-e73ab9c101da' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 10:58:48
	System	15 Oct 2020 10:58:48

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:31', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8411c480-58de-4804-81d6-e73ab9c101da' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 10:58:48
	System	15 Oct 2020 10:58:48

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:33', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8411c480-58de-4804-81d6-e73ab9c101da' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 10:58:48
	System	15 Oct 2020 10:58:48

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:35', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8411c480-58de-4804-81d6-e73ab9c101da' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 10:58:48
	System	15 Oct 2020 10:58:48

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:38', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8411c480-58de-4804-81d6-e73ab9c101da' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 10:58:48
	System	15 Oct 2020 10:58:48

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:42', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8411c480-58de-4804-81d6-e73ab9c101da' User entered 'No (N)'	(b) (4), (b) (6) System	15 Oct 2020 10:58:48
	System	15 Oct 2020 10:58:48

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T05:58:45', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '8411c480-58de-4804-81d6-e73ab9c101da' User entered '15 Oct 2020 05:58'	(b) (4), (b) (6) System	15 Oct 2020 10:58:48
	System	15 Oct 2020 10:58:48

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 13:03:19
User entered 'Day 7'	System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '71ce5f68-deba-4a74-b036-d12824245908' User entered 'None (0)'	(b) (4), (b) (6) System	16 Oct 2020 02:42:08
	System	16 Oct 2020 02:42:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:49', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '71ce5f68-deba-4a74-b036-d12824245908' User entered 'None (0)'	(b) (4), (b) (6) System	16 Oct 2020 02:42:08
	System	16 Oct 2020 02:42:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '71ce5f68-deba-4a74-b036-d12824245908' User entered 'None (0)'	(b) (4), (b) (6) System	16 Oct 2020 02:42:08
	System	16 Oct 2020 02:42:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:53', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '71ce5f68-deba-4a74-b036-d12824245908' User entered 'None (0)'	(b) (4), (b) (6) System	16 Oct 2020 02:42:08
	System	16 Oct 2020 02:42:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:56', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '71ce5f68-deba-4a74-b036-d12824245908' User entered 'None (0)'	(b) (4), (b) (6) System	16 Oct 2020 02:42:08
	System	16 Oct 2020 02:42:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:41:59', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '71ce5f68-deba-4a74-b036-d12824245908' User entered 'None (0)'	(b) (4), (b) (6) System	16 Oct 2020 02:42:08
	System	16 Oct 2020 02:42:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:42:04', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '71ce5f68-deba-4a74-b036-d12824245908' User entered 'No (N)'	(b) (4), (b) (6) System	16 Oct 2020 02:42:08
	System	16 Oct 2020 02:42:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-10-15T21:42:06', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '71ce5f68-deba-4a74-b036-d12824245908' User entered '15 Oct 2020 21:42'	(b) (4), (b) (6) System	16 Oct 2020 02:42:08
	System	16 Oct 2020 02:42:08

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:14:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 13:03:19

US3242314

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	19 Oct 2020 14:21:56
	(b) (4)	

US3242314

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered '18 Oct 2020'	Erynn McKinley (b) (4)	19 Oct 2020 14:21:56
	(b) (4)	

US3242314

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	19 Oct 2020 14:21:56
	(b) (4)	

US3242314

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered empty.	Erynn McKinley (b) (4)	19 Oct 2020 14:21:56
	(b) (4)	

US3242314

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	19 Oct 2020 14:21:59
	(b) (4)	

US3242314

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
User entered 'I'	(b) (4), (b) (6) System	19 Oct 2020 14:21:59

US3242314

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	02 Nov 2020 12:53:06

US3242314

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered '26 Oct 2020'	Donna Toepfer (b) (4)	02 Nov 2020 12:53:06

US3242314

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	02 Nov 2020 12:53:06

US3242314

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered empty.	Donna Toepfer (b) (4)	02 Nov 2020 12:53:06

US3242314

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	02 Nov 2020 12:53:10

US3242314

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:00
User entered 'I'	(b) (4), (b) (6) System	02 Nov 2020 12:53:10

US3242314

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	02 Nov 2020 12:53:27

US3242314

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '30 Oct 2020'	Donna Toepfer (b) (4)	02 Nov 2020 12:53:27

US3242314

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	02 Nov 2020 12:53:27

US3242314

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered empty.	Donna Toepfer (b) (4)	02 Nov 2020 12:53:27

US3242314

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	02 Nov 2020 12:58:44

US3242314

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'I'	(b) (4), (b) (6) System	02 Nov 2020 12:58:44

US3242314

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:20

US3242314

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered '5 Nov 2020'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:20

US3242314

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:20

US3242314

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'VISIT3'	(b) (4), (b) (6) System	05 Nov 2020 14:05:20

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered '5 Nov 2020'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered '08:19'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered '5 Nov 2020 08:19'	(b) (4), (b) (6) System	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered '97.0' F	Donna Toepfer (b) (4)	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered empty.	Donna Toepfer (b) (4)	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered '68'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'bpm'	(b) (4), (b) (6) System	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered '16'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'breaths/min'	(b) (4), (b) (6) System	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered '126'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'mmHg'	(b) (4), (b) (6) System	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered '72'	Donna Toepfer (b) (4)	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'mmHg'	(b) (4), (b) (6) System	05 Nov 2020 14:05:50

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 07:21:36

US3242314

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 07:21:36

US3242314

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered 'No (N)'	Donna Toepfer (b) (4)	05 Nov 2020 14:06:00

US3242314

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered empty.	Donna Toepfer (b) (4)	05 Nov 2020 14:06:00

US3242314

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	05 Nov 2020 14:06:13

US3242314

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered '5 Nov 2020'	Donna Toepfer (b) (4)	05 Nov 2020 14:06:13

US3242314

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered '08:48'	Donna Toepfer (b) (4)	05 Nov 2020 14:06:13

US3242314

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered '5 Nov 2020 08:48'	(b) (4), (b) (6) System	05 Nov 2020 14:06:13

US3242314

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	05 Nov 2020 14:06:18

US3242314

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'I'	(b) (4), (b) (6) System	05 Nov 2020 14:06:18

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 64'	System	10 Sep 2020 16:23:29

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-11T10:31:39', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '004b3358-a9d6-4150-a7fa-d0fe115ec3fd' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Nov 2020 15:32:33
	System	11 Nov 2020 15:32:33

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-11T10:31:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '004b3358-a9d6-4150-a7fa-d0fe115ec3fd'	(b) (4), (b) (6)	
	System	11 Nov 2020 15:32:33
User entered 'No (N)'	System	11 Nov 2020 15:32:33

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-11T10:31:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '004b3358-a9d6-4150-a7fa-d0fe115ec3fd'	(b) (4), (b) (6)	
User entered 'No (N)'	System	11 Nov 2020 15:32:33

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-11T10:32:13', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '004b3358-a9d6-4150-a7fa-d0fe115ec3fd'	(b) (4), (b) (6)	
	System	11 Nov 2020 15:32:33
User entered 'No (N)'	System	11 Nov 2020 15:32:33

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-11T10:32:28', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '004b3358-a9d6-4150-a7fa-d0fe115ec3fd' User entered '11 Nov 2020 10:32:28'	(b) (4), (b) (6) System	11 Nov 2020 15:32:33
	System	11 Nov 2020 15:32:33

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 16:23:29

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 16:23:29

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered 'Day 71'	System	10 Sep 2020 16:23:29

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-17T17:31:49', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '1781ed1d-fb69-47c9-b791-035b7aaae170' User entered 'No (N)'	(b) (4), (b) (6) System	17 Nov 2020 22:33:19
	System	17 Nov 2020 22:33:19

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-17T17:32:40', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '1781ed1d-fb69-47c9-b791-035b7aaae170'	(b) (4), (b) (6)	
User entered 'No (N)'	System	17 Nov 2020 22:33:19

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-17T17:33:14', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '1781ed1d-fb69-47c9-b791-035b7aaae170' User entered '17 Nov 2020 17:33:14'	(b) (4), (b) (6) System	17 Nov 2020 22:33:19
	System	17 Nov 2020 22:33:19

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 16:23:29

US3242314

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:31:51
	(b) (4), (b) (6)	
Data entry locked.	System	10 Sep 2020 16:23:29
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 16:23:29

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-24T15:11:54', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fb9fed4d-a2e0-4086-90b3-4f94399a7ee1'	System	24 Nov 2020 20:12:15
User entered 'No (N)'	System	24 Nov 2020 20:12:15

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-24T15:12:06', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fb9fed4d-a2e0-4086-90b3-4f94399a7ee1'	System	24 Nov 2020 20:12:15
User entered 'No (N)'	System	24 Nov 2020 20:12:15

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-24T15:12:12', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'fb9fed4d-a2e0-4086-90b3-4f94399a7ee1' User entered '24 Nov 2020 15:12:12'	System	24 Nov 2020 20:12:15
	System	24 Nov 2020 20:12:15

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-30T11:42:53', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '99a26ff1-1872-45a9-b4dd-317985402ee3' User entered 'No (N)'	System	30 Nov 2020 16:43:12
	System	30 Nov 2020 16:43:12

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-30T11:43:04', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '99a26ff1-1872-45a9-b4dd-317985402ee3' User entered 'No (N)'	System	30 Nov 2020 16:43:12

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-11-30T11:43:09', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '99a26ff1-1872-45a9-b4dd-317985402ee3' User entered '30 Nov 2020 11:43:09'	System	30 Nov 2020 16:43:12
	System	30 Nov 2020 16:43:12

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-05T07:33:59', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '631846b7-d42a-48e7-ac55-0c722c62ec1a' User entered 'No (N)'	System	05 Dec 2020 12:34:27
	System	05 Dec 2020 12:34:27

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-05T07:34:04', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '631846b7-d42a-48e7-ac55-0c722c62ec1a'	System	05 Dec 2020 12:34:27
User entered 'No (N)'	System	05 Dec 2020 12:34:27

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-05T07:34:26', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '631846b7-d42a-48e7-ac55-0c722c62ec1a' User entered '05 Dec 2020 07:34:26'	System	05 Dec 2020 12:34:27
	System	05 Dec 2020 12:34:27

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-13T16:43:40', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afed72cd-e9b5-4aaf-b462-48b86f3bf9f6'	System	13 Dec 2020 21:44:11
User entered 'No (N)'	System	13 Dec 2020 21:44:11

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-13T16:44:02', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afed72cd-e9b5-4aaf-b462-48b86f3bf9f6'	System	13 Dec 2020 21:44:11
User entered 'No (N)'	System	13 Dec 2020 21:44:11

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-13T16:44:06', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'afed72cd-e9b5-4aaf-b462-48b86f3bf9f6'	System	13 Dec 2020 21:44:11
User entered '13 Dec 2020 16:44:06'	System	13 Dec 2020 21:44:11

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-19T16:27:59', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '54edd65d-132a-4d36-95c9-2a4d10660e25'	System	19 Dec 2020 21:28:14
User entered 'No (N)'	System	19 Dec 2020 21:28:14

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-19T16:28:04', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '54edd65d-132a-4d36-95c9-2a4d10660e25'	System	19 Dec 2020 21:28:14
User entered 'No (N)'	System	19 Dec 2020 21:28:14

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-19T16:28:09', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '54edd65d-132a-4d36-95c9-2a4d10660e25' User entered '19 Dec 2020 16:28:09'	System	19 Dec 2020 21:28:14
	System	19 Dec 2020 21:28:14

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-26T08:08:49', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '70af314b-8261-4362-b471-a4f6e9c1289e' User entered 'No (N)'	System	26 Dec 2020 13:09:11
	System	26 Dec 2020 13:09:11

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-26T08:09:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '70af314b-8261-4362-b471-a4f6e9c1289e' User entered 'No (N)'	System	26 Dec 2020 13:09:11
	System	26 Dec 2020 13:09:11

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2020-12-26T08:09:06', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '70af314b-8261-4362-b471-a4f6e9c1289e' User entered '26 Dec 2020 08:09:06'	System	26 Dec 2020 13:09:11
	System	26 Dec 2020 13:09:11

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-02T05:50:36', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e9d00386-2409-42c8-a546-5eba109b9179'	System	02 Jan 2021 10:50:57
User entered 'No (N)'	System	02 Jan 2021 10:50:57

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-02T05:50:47', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e9d00386-2409-42c8-a546-5eba109b9179'	System	02 Jan 2021 10:50:57
User entered 'No (N)'	System	02 Jan 2021 10:50:57

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-02T05:50:52', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e9d00386-2409-42c8-a546-5eba109b9179' User entered '02 Jan 2021 05:50:52'	System	02 Jan 2021 10:50:57

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-09T06:34:43', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '78dd857e-9a4e-443f-87a2-8214ff1da874'	System	09 Jan 2021 11:34:59
User entered 'No (N)'	System	09 Jan 2021 11:34:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-09T06:34:48', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '78dd857e-9a4e-443f-87a2-8214ff1da874'	System	09 Jan 2021 11:34:59
User entered 'No (N)'	System	09 Jan 2021 11:34:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-09T06:34:53', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '78dd857e-9a4e-443f-87a2-8214ff1da874' User entered '09 Jan 2021 06:34:53'	System	09 Jan 2021 11:34:59
	System	09 Jan 2021 11:34:59

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-17T08:53:50', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ce5c6ed5-64a1-409e-b964-977111a0d4d9'	System	17 Jan 2021 13:54:08
User entered 'No (N)'	System	17 Jan 2021 13:54:08

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-17T08:53:56', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ce5c6ed5-64a1-409e-b964-977111a0d4d9'	System	17 Jan 2021 13:54:08
User entered 'No (N)'	System	17 Jan 2021 13:54:08

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-17T08:54:06', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'ce5c6ed5-64a1-409e-b964-977111a0d4d9' User entered '17 Jan 2021 08:54:06'	System	17 Jan 2021 13:54:08
	System	17 Jan 2021 13:54:08

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-23T10:15:42', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '9c36bfc7-3788-4c12-8600-a2d7c64c39d1'	System	23 Jan 2021 15:15:54
User entered 'No (N)'	System	23 Jan 2021 15:15:54

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-23T10:15:46', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '9c36bfc7-3788-4c12-8600-a2d7c64c39d1'	System	23 Jan 2021 15:15:54
User entered 'No (N)'	System	23 Jan 2021 15:15:54

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-23T10:15:52', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '9c36bfc7-3788-4c12-8600-a2d7c64c39d1' User entered '23 Jan 2021 10:15:52'	System	23 Jan 2021 15:15:54
	System	23 Jan 2021 15:15:54

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-30T05:51:01', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'aeb6d63b-89b9-487d-9397-73b9da786dc3'	System	30 Jan 2021 10:52:42
User entered 'Yes (Y)'	System	30 Jan 2021 10:52:42

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-30T05:50:52', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'aeb6d63b-89b9-487d-9397-73b9da786dc3'	System	30 Jan 2021 10:52:42
User entered 'No (N)'	System	30 Jan 2021 10:52:42

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-30T05:50:51', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'aeb6d63b-89b9-487d-9397-73b9da786dc3'	System	30 Jan 2021 10:52:42
User entered 'No (N)'	System	30 Jan 2021 10:52:42

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-30T05:50:50', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'aeb6d63b-89b9-487d-9397-73b9da786dc3'	System	30 Jan 2021 10:52:42
User entered 'Yes (Y)'	System	30 Jan 2021 10:52:42

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Please 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-30T05:51:22', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'aeb6d63b-89b9-487d-9397-73b9da786dc3'	System	30 Jan 2021 10:52:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 10:52:42

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-01-30T05:52:32', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'aeb6d63b-89b9-487d-9397-73b9da786dc3' User entered '30 Jan 2021 05:52:32'	System	30 Jan 2021 10:52:42

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-06T07:31:06', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b0e17320-8450-4af0-a4ff-b8817dc0339b'	System	06 Feb 2021 12:31:24
User entered 'No (N)'	System	06 Feb 2021 12:31:24

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-06T07:31:12', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b0e17320-8450-4af0-a4ff-b8817dc0339b'	System	06 Feb 2021 12:31:24
User entered 'No (N)'	System	06 Feb 2021 12:31:24

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-06T07:31:20', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'b0e17320-8450-4af0-a4ff-b8817dc0339b' User entered '06 Feb 2021 07:31:20'	System	06 Feb 2021 12:31:24
	System	06 Feb 2021 12:31:24

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-15T04:40:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e18d1546-44b9-45be-aa3f-845c31965fe9'	System	15 Feb 2021 09:40:49
User entered 'Yes (Y)'	System	15 Feb 2021 09:40:49

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-15T04:40:04', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e18d1546-44b9-45be-aa3f-845c31965fe9' User entered 'No (N)'	System	15 Feb 2021 09:40:49
	System	15 Feb 2021 09:40:49

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-15T04:40:09', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e18d1546-44b9-45be-aa3f-845c31965fe9' User entered 'No (N)'	System	15 Feb 2021 09:40:49
	System	15 Feb 2021 09:40:49

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-15T04:40:17', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e18d1546-44b9-45be-aa3f-845c31965fe9' User entered 'Yes (Y)'	System	15 Feb 2021 09:40:49
	System	15 Feb 2021 09:40:49

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Please 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-15T04:40:29', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e18d1546-44b9-45be-aa3f-845c31965fe9'	System	15 Feb 2021 09:40:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Feb 2021 09:40:49

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-15T04:40:35', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e18d1546-44b9-45be-aa3f-845c31965fe9' User entered '15 Feb 2021 04:40:35'	System	15 Feb 2021 09:40:49
	System	15 Feb 2021 09:40:49

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-20T07:30:32', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0d9493b1-5f1a-4ea5-86c2-59a13f32c457'	System	20 Feb 2021 12:30:44
User entered 'No (N)'	System	20 Feb 2021 12:30:44

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-20T07:30:38', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0d9493b1-5f1a-4ea5-86c2-59a13f32c457'	System	20 Feb 2021 12:30:44
User entered 'No (N)'	System	20 Feb 2021 12:30:44

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-02-20T07:30:43', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '0d9493b1-5f1a-4ea5-86c2-59a13f32c457'	System	20 Feb 2021 12:30:44
User entered '20 Feb 2021 07:30:43'	System	20 Feb 2021 12:30:44

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-01T14:48:06-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'a50d10ef-761e-42f4-97a0-647ff826ad49'	System	01 Mar 2021 19:48:15
User entered 'No (N)'	System	01 Mar 2021 19:48:15

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-01T14:48:08-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'a50d10ef-761e-42f4-97a0-647ff826ad49'	System	01 Mar 2021 19:48:15
User entered 'No (N)'	System	01 Mar 2021 19:48:15

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-01T14:48:13-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'a50d10ef-761e-42f4-97a0-647ff826ad49'	System	01 Mar 2021 19:48:15
User entered '01 Mar 2021 19:48:13'	System	01 Mar 2021 19:48:15

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-06T06:52:13-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'bbb77e57-3f47-41af-87eb-3531d5487309' User entered 'No (N)'	System	06 Mar 2021 11:52:22
	System	06 Mar 2021 11:52:22

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-06T06:52:16-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'bbb77e57-3f47-41af-87eb-3531d5487309'	System	06 Mar 2021 11:52:22
User entered 'No (N)'	System	06 Mar 2021 11:52:22

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-06T06:52:20-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'bbb77e57-3f47-41af-87eb-3531d5487309' User entered '06 Mar 2021 06:52:20'	System	06 Mar 2021 11:52:22
	System	06 Mar 2021 11:52:22

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-14T08:56:36-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2b2a21d9-0c2d-469e-85fd-65808cb20fa0'	System	14 Mar 2021 12:56:48
User entered 'No (N)'	System	14 Mar 2021 12:56:48

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-14T08:56:40-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2b2a21d9-0c2d-469e-85fd-65808cb20fa0'	System	14 Mar 2021 12:56:48
User entered 'No (N)'	System	14 Mar 2021 12:56:48

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-14T08:56:43-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2b2a21d9-0c2d-469e-85fd-65808cb20fa0' User entered '14 Mar 2021 08:56:43'	System	14 Mar 2021 12:56:48
	System	14 Mar 2021 12:56:48

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-20T07:14:22-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '6e97252c-465d-4ccd-9f83-bf960ebd3763'	System	20 Mar 2021 11:14:38
User entered 'No (N)'	System	20 Mar 2021 11:14:38

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-20T07:14:29-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '6e97252c-465d-4ccd-9f83-bf960ebd3763'	System	20 Mar 2021 11:14:38
User entered 'No (N)'	System	20 Mar 2021 11:14:38

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-20T07:14:35-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '6e97252c-465d-4ccd-9f83-bf960ebd3763' User entered '20 Mar 2021 07:14:35'	System	20 Mar 2021 11:14:38
	System	20 Mar 2021 11:14:38

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-27T11:59:40-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '91057e2f-1e57-42cc-a989-00ca184ed636'	System	31 Mar 2021 11:39:04
User entered 'No (N)'	System	31 Mar 2021 11:39:04

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-27T11:59:47-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '91057e2f-1e57-42cc-a989-00ca184ed636'	System	31 Mar 2021 11:39:04
User entered 'No (N)'	System	31 Mar 2021 11:39:04

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-27T11:59:53-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '91057e2f-1e57-42cc-a989-00ca184ed636'	System	31 Mar 2021 11:39:04
User entered '27 Mar 2021 11:59:53'	System	31 Mar 2021 11:39:04

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-03T06:00:17-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e1308600-7bfa-4e4c-a965-e64cbfc54f2c'	System	03 Apr 2021 10:00:28
User entered 'No (N)'	System	03 Apr 2021 10:00:28

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-03T06:00:20-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e1308600-7bfa-4e4c-a965-e64cbfc54f2c'	System	03 Apr 2021 10:00:28
User entered 'No (N)'	System	03 Apr 2021 10:00:28

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-03T06:00:26-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'e1308600-7bfa-4e4c-a965-e64cbfc54f2c' User entered '03 Apr 2021 06:00:26'	System	03 Apr 2021 10:00:28
	System	03 Apr 2021 10:00:28

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-10T05:51:09-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '62506ce9-066a-4f1f-b42d-1ba3eaa70803'	System	10 Apr 2021 09:51:22
User entered 'No (N)'	System	10 Apr 2021 09:51:22

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-10T05:51:12-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '62506ce9-066a-4f1f-b42d-1ba3eaa70803' User entered 'No (N)'	System	10 Apr 2021 09:51:22

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-10T05:51:16-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '62506ce9-066a-4f1f-b42d-1ba3eaa70803' User entered '10 Apr 2021 05:51:16'	System	10 Apr 2021 09:51:22
	System	10 Apr 2021 09:51:22

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-17T07:09:55-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '450bedfa-3059-4371-ae55-4f3b60b665c1' User entered 'No (N)'	System	17 Apr 2021 11:10:06
	System	17 Apr 2021 11:10:06

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-17T07:09:59-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '450bedfa-3059-4371-ae55-4f3b60b665c1' User entered 'No (N)'	System	17 Apr 2021 11:10:06
	System	17 Apr 2021 11:10:06

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-17T07:10:03-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '450bedfa-3059-4371-ae55-4f3b60b665c1' User entered '17 Apr 2021 07:10:03'	System	17 Apr 2021 11:10:06
	System	17 Apr 2021 11:10:06

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-26T08:23:55-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2635c241-38fb-4fdf-955a-c3d019037b2b' User entered 'No (N)'	System	26 Apr 2021 12:24:07
	System	26 Apr 2021 12:24:07

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-26T08:23:59-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2635c241-38fb-4fdf-955a-c3d019037b2b'	System	26 Apr 2021 12:24:07
User entered 'No (N)'	System	26 Apr 2021 12:24:07

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-04-26T08:24:02-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '2635c241-38fb-4fdf-955a-c3d019037b2b' User entered '26 Apr 2021 08:24:02'	System	26 Apr 2021 12:24:07
	System	26 Apr 2021 12:24:07

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-05-01T18:01:05-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'cbe3596e-bbf8-4fd1-8e36-ffd4c295001f' User entered 'No (N)'	System	01 May 2021 22:04:44
	System	01 May 2021 22:04:44

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Have you been exposed to someone with 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 (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-05-01T18:01:08-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'cbe3596e-bbf8-4fd1-8e36-ffd4c295001f' User entered 'No (N)'	System	01 May 2021 22:04:44

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-05-01T18:01:12-04:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: 'cbe3596e-bbf8-4fd1-8e36-ffd4c295001f' User entered '01 May 2021 18:01:12'	System	01 May 2021 22:04:44
	System	01 May 2021 22:04:44

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:03:16

US3242314

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:03:16
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:03:16

US3242314

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:14:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:22:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-01T14:48:20-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '6a6222bd-8fd5-45eb-874a-f6c6720c2200'	System	01 Mar 2021 19:48:33
User entered 'No (N)'	System	01 Mar 2021 19:48:33

US3242314

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:14:28

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:22:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15EF7FDD-B1EA-4ABD-B1D6-3068D825148B)', Time: '2021-03-01T14:48:29-05:00', User OID: 'PatientReportedOutcome (US3242314)', ODM File OID: '6a6222bd-8fd5-45eb-874a-f6c6720c2200' User entered '01 Mar 2021 19:48:29'	System	01 Mar 2021 19:48:33
	System	01 Mar 2021 19:48:33

US3242314

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	01 Dec 2020 22:23:46
	(b) (4)	

US3242314

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered '1 Dec 2020'	Erynn McKinley (b) (4)	01 Dec 2020 22:23:46
	(b) (4)	

US3242314

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	01 Dec 2020 22:23:46
	(b) (4)	

US3242314

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered empty.	Erynn McKinley (b) (4)	01 Dec 2020 22:23:46
	(b) (4)	

US3242314

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	01 Dec 2020 22:23:49
	(b) (4)	

US3242314

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:36
User entered 'I'	(b) (4), (b) (6) System	01 Dec 2020 22:23:49

US3242314

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:44
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Jan 2021 22:06:51

US3242314

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:44
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '05 Jan 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	06 Jan 2021 16:21:47
User entered '4 Jan 2021'	Erynn McKinley (b) (4)	05 Jan 2021 22:06:51

US3242314

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:44
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	05 Jan 2021 22:06:51

US3242314

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:47:44
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered empty.	Erynn McKinley (b) (4)	05 Jan 2021 22:06:51

US3242314

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:47:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	05 Jan 2021 22:06:56

US3242314

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
User entered 'I'	(b) (4), (b) (6) System	05 Jan 2021 22:06:56

US3242314

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:47:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:44:27
User closed query 'Per CDM: Response noted, please update when data becomes available. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 08:52:54
Query 'Per CDM: Response noted, please update when data becomes available. Thank you' answered with 'will do' (Site from DM).	Donna Toepfer (b) (4)	06 Jan 2021 22:13:45
User opened query 'Per CDM: Response noted, please update when data becomes available. Thank you' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 21:38:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Jan 2021 21:37:46
Query 'Data is required. Please complete.' answered with 'visit not occurred' (Site from System).	Donna Toepfer (b) (4)	06 Jan 2021 16:22:40
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:22:02
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	06 Jan 2021 16:22:02
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	06 Jan 2021 16:22:02
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	06 Jan 2021 15:59:22
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 15:59:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 15:58:56

US3242314

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:47:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '3 Feb 2021' reason for change: Data Entry Error	Erynn McKinley (b) (4)	03 Feb 2021 19:44:27
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	06 Jan 2021 15:59:22
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	06 Jan 2021 15:59:22
User entered empty; reason for change Data Entry Error	Erynn McKinley (b) (4)	06 Jan 2021 15:59:22
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	06 Jan 2021 15:58:56
User entered '5 Jan 2021'	Erynn McKinley (b) (4)	06 Jan 2021 15:58:56

US3242314

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:47:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:44:27
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	06 Jan 2021 16:22:02
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 15:59:32
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 15:58:56

US3242314

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:47:57
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	06 Jan 2021 16:22:02
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	06 Jan 2021 15:59:32
User entered empty.	Erynn McKinley (b) (4) (b) (4)	06 Jan 2021 15:58:56

US3242314

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Mar 2021 16:04:30
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:44:31

US3242314

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
User entered 'I'	(b) (4), (b) (6) System	03 Feb 2021 19:44:31

US3242314

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:48:09
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:29:01
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 15:36:34

US3242314

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:48:09
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:29:01
User entered '08 Mar 2021'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 15:36:34

US3242314

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:48:09
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:29:01
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 15:36:34

US3242314

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:48:09
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:29:01
User entered empty.	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 15:36:34

US3242314

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Mar 2021 16:04:30
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:29:01
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	08 Mar 2021 15:36:36

US3242314

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:16:22
User entered 'I'	(b) (4), (b) (6) System	08 Mar 2021 15:36:36

US3242314

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:05
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	07 Apr 2021 13:56:56

US3242314

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:05
User entered '07 Apr 2021'	Erynn McKinley (b) (4)	07 Apr 2021 13:56:56

US3242314

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:05
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	07 Apr 2021 13:56:56

US3242314

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User entered 'VISIT4'	System	07 Apr 2021 13:56:56

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:21
User entered 'No (N)'	Erynn McKinley (b) (4)	07 Apr 2021 13:57:01
	(b) (4)	

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:21
User entered empty.	Erynn McKinley (b) (4) (b) (4)	07 Apr 2021 13:57:01

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:21
User entered empty.	Erynn McKinley (b) (4) (b) (4)	07 Apr 2021 13:57:01

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User entered empty.	(b) (4), (b) (6) System	07 Apr 2021 13:57:01

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:21
User entered empty.	Erynn McKinley (b) (4)	07 Apr 2021 13:57:01
	(b) (4)	

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:21
User entered empty.	Erynn McKinley (b) (4)	07 Apr 2021 13:57:01
	(b) (4)	

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:21
User entered empty.	Erynn McKinley (b) (4)	07 Apr 2021 13:57:01
	(b) (4)	

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:21
User entered empty.	Erynn McKinley (b) (4) (b) (4)	07 Apr 2021 13:57:01

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User entered empty.	(b) (4), (b) (6) System	07 Apr 2021 13:57:01

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:21
User entered empty.	Erynn McKinley (b) (4) (b) (4)	07 Apr 2021 13:57:01

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User entered empty.	(b) (4), (b) (6) System	07 Apr 2021 13:57:01

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:21
User entered empty.	Erynn McKinley (b) (4)	07 Apr 2021 13:57:01
	(b) (4)	

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User entered empty.	(b) (4), (b) (6) System	07 Apr 2021 13:57:01

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:21
User entered empty.	Erynn McKinley (b) (4)	07 Apr 2021 13:57:01
	(b) (4)	

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:41
User entered empty.	(b) (4), (b) (6) System	07 Apr 2021 13:57:01

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 22:16:41

US3242314

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:28

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 22:16:41

US3242314

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:54:33
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	07 Apr 2021 13:57:11

US3242314

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:54:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	07 Apr 2021 13:57:11

US3242314

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:54:18
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	07 Apr 2021 13:57:25
	(b) (4)	

US3242314

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:54:18
User entered '07 Apr 2021'	Erynn McKinley (b) (4) (b) (4)	07 Apr 2021 13:57:25

US3242314

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:54:18
User entered '08:15'	Erynn McKinley (b) (4) (b) (4)	07 Apr 2021 13:57:25

US3242314

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:26
User entered '07 Apr 2021 08:15'	(b) (4), (b) (6) System	07 Apr 2021 13:57:25

US3242314

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:18:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:53:58
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	07 Apr 2021 13:57:29

US3242314

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:26
User entered 'I'	(b) (4), (b) (6) System	07 Apr 2021 13:57:29

US3242314

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

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:26:56
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:30:43

US3242314

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

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:26:56
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:23:50
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:30:43

US3242314

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

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:26:56
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:23:52
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:30:43

US3242314

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

Form: Visit Date

Generated On: 09 Jun 2021 16:14:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	12 Jan 2021 16:30:43

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:24:24
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:31:46

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:24:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:48
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:29:01
User entered '0'	Erynn McKinley (b) (4)	09 Mar 2021 17:08:17
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 08:45:55

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:24:34
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:31:46

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:25:57
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:48
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:29:01
User entered 'Amendment 6 or later (Amendment 6 or later)'	Erynn McKinley (b) (4)	09 Mar 2021 17:08:17
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:45:55

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:25:59
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:31:46

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:01
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:31:46

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:03
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 04:31:50
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:31:46

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:04
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 04:31:50
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:31:46

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:06
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:31:46

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
User entered empty.	(b) (4), (b) (6) System	12 Jan 2021 16:31:46

US3242314

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

Form: Unblinding

Generated On: 09 Jun 2021 16:14:28

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
User entered empty.	(b) (4), (b) (6) System	12 Jan 2021 16:31:46

US3242314

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:05
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:15
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:32:12

US3242314

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:05
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:17
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:32:12

US3242314

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:05
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:19
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '08:33'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:32:12

US3242314

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
User entered '12 Jan 2021 08:33'	(b) (4), (b) (6) System	12 Jan 2021 16:32:12

US3242314

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:11
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:23
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:01
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:32:29

US3242314

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:11
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:25
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:01
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:32:29

US3242314

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 20:27:11
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:26:26
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 05:59:01
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '08:28'	Erynn McKinley (b) (4) (b) (4)	12 Jan 2021 16:32:29

US3242314

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:14:28

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:51:10
User entered '12 Jan 2021 08:28'	(b) (4), (b) (6) System	12 Jan 2021 16:32:29

US3242314

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:14:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:33:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Nov 2020 14:06:43
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 15:31:02

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:08
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:33:25
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:22:42
User entered 'USA-US067-2020-mRNA-1273-P301000012'	System	16 Nov 2020 20:22:34
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 20:22:34

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Adenocarcinoma of prostate - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:04:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:04:46
Data point term sent to Coder	System	13 Nov 2020 14:08:20
User entered 'Prostatic Adenocarcinoma (Gleason Score 3+4+=7)'	Donna Toepfer (b) (4) (b) (4) (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:17
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:19
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:21
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'No (N)'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:26
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered '06 Nov 2020'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:30
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:32
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:34:45
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 14:34:24
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 16:47:42
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 02:18:57
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	22 Jan 2021 16:20:13
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 12:23:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
User closed query 'PV Query: Please provide the event end date, when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:37:04

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available.' answered with 'ongoing at this time' (Site from Safety).	Donna Toepfer (b) (4)	23 Nov 2020 21:00:33
User opened query 'PV Query: Please provide the event end date, when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:22:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:38
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:40
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User closed query 'PV Query: Per Vaccine Grading Toxicity Scale any event that is 'Potentially Life-Threatening' should be Grade 4. Please evaluate this event and update severity assessment accordingly. ' (Site from Safety). Query 'PV Query: Per Vaccine Grading Toxicity Scale any event that is 'Potentially Life-Threatening' should be Grade 4. Please evaluate this event and update severity assessment accordingly. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 19:16:56
DataPoint Un-verified.	Donna Toepfer (b) (4)	01 Dec 2020 16:09:51
DataPoint Un-verified.	Donna Toepfer (b) (4)	01 Dec 2020 16:00:37
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Dec 2020 16:00:37
User opened query 'PV Query: Per Vaccine Grading Toxicity Scale any event that is 'Potentially Life-Threatening' should be Grade 4. Please evaluate this event and update severity assessment accordingly. ' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 12:21:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:43
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:47
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
User closed query 'PV Query: Please confirm if event should be life threatening or medically significant as intensity is grade 3, and update as applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:37:06
Query 'PV Query: Please confirm if event should be life threatening or medically significant as intensity is grade 3, and update as applicable.' answered with 'correct as entered by PI' (Site from Safety).	Donna Toepfer (b) (4)	23 Nov 2020 21:01:09
User opened query 'PV Query: Please confirm if event should be life threatening or medically significant as intensity is grade 3, and update as applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:53
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered '1'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:38:59
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:01
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:04
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:06
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:10
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:14
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:22
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:24
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:27
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'Not Applicable (NOT APPLICABLE)'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:14
	(b) (4), (b) (6)	
User closed query 'Per CDM: As per your query response no update has been there, please review and update, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 10:32:48
Query 'Per CDM: As per your query response no update has been there, please review and update, else clarify.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	07 Apr 2021 20:37:26
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		07 Apr 2021 20:37:17
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Apr 2021 20:37:17
User entered '0' reason for change: Data Entry Error	Donna Toepfer (b) (4)	07 Apr 2021 20:37:17
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	01 Mar 2021 22:04:15
User opened query 'Per CDM: As per your query response no update has been there, please review and update, else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 13:02:43
User closed query 'Per DM CLR: Other Action Taken = None, however there is a ConProc recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 13:02:43
Query 'Per DM CLR: Other Action Taken = None, however there is a ConProc recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	23 Feb 2021 19:55:12
User opened query 'Per DM CLR: Other Action Taken = None, however there is a ConProc recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 12:29:17
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:08:26

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

None

Audit	User	Time (GMT)
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		22 Jan 2021 16:25:32
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	22 Jan 2021 16:20:38
DataPoint Un-verified.	Donna Toepfer (b) (4)	22 Jan 2021 16:20:38
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Jan 2021 16:20:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:39:58
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered '0'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:35:01
DataPoint Un-verified.	(b) (4), (b) (6) Donna Toepfer (b) (4)	01 Mar 2021 22:04:15
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Mar 2021 22:04:15
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:08:26
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:57:45
DataPoint Un-verified.	Donna Toepfer (b) (4)	22 Jan 2021 16:25:32
User entered '0' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Jan 2021 16:25:32
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'subject will be having prostatectomy on 1/27/2021, will update procedures when available' (Site from DM).	Donna Toepfer (b) (4)	22 Jan 2021 16:14:20
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 00:10:44
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:40:03

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
	(b) (4), (b) (6)	
User entered 'I'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 12:23:25
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:37:11
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'ongoing at this time' (Site from Safety).	Donna Toepfer (b) (4)	23 Nov 2020 21:01:29
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:23:19
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:40:08
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:20:55
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:40:11
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:26:51
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. any additional imaging). Please include units and reference ranges if applicable. If the only lab and imaging performed was PSA and biopsy, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 17:00:06
User closed query 'PV Query: Please confirm subject had prostatectomy on 27 Jan 2021. If not, please provide date of surgery.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 17:00:04
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. any additional imaging). Please include units and reference ranges if applicable. If the only lab and imaging performed was PSA and biopsy, please state so in your response.' answered with 'only lab and imaging performed was PSA and biopsy' (Site from Safety).	Donna Toepfer (b) (4)	10 Feb 2021 14:51:39
Query 'PV Query: Please confirm subject had prostatectomy on 27 Jan 2021. If not, please provide date of surgery.' answered with 'confirm, surgery on 27Jan2021' (Site from Safety).	Donna Toepfer (b) (4)	10 Feb 2021 14:51:10
User opened query 'PV Query: Please confirm subject had prostatectomy on 27 Jan 2021. If not, please provide date of surgery.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 16:49:23
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. any additional imaging). Please include units and reference ranges if applicable. If the only lab and imaging performed was PSA and biopsy, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 16:47:09
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:08:26
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 02:19:06
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. any additional imaging). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 02:19:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

1684 of 1990

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WENT TO UROLOGIST ON 22OCT2020. PROSTATE BIOPSY WAS SCHEDULED DUE TO INCREASING PSA LEVELS OVER LAST SEVERAL YEARS. MEDICAL RECORDS RECEIVED TO REVEAL PROSTATIC ADENOCARCINOMA. PER PI, THIS DOES MEET SERIOUS CRITERIA. WILL FOLLOW SUBJECT FOR PLAN OF TREATMENT. SUBJECT STATES HE HAD SURGICAL CONSULT ON 30NOV2020 AND WILL HAVE RADIATION CONSULT ON 03DEC2020, HE WILL THEN DETERMINE THE BEST COURSE OF TREATMENT. UPDATE: RADIATION AND SURGICAL CONSULT COMPLETED AND SUBJECT IS SCHEDULED FOR PROSTATECTOMY 1/27/2021.' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Jan 2021 16:26:43
User entered 'SUBJECT WENT TO UROLOGIST ON 22OCT2020. PROSTATE BIOPSY WAS SCHEDULED DUE TO INCREASING PSA LEVELS OVER LAST SEVERAL YEARS. MEDICAL RECORDS RECEIVED TO REVEAL PROSTATIC ADENOCARCINOMA. PER PI, THIS DOES MEET SERIOUS CRITERIA. WILL FOLLOW SUBJECT FOR PLAN OF TREATMENT. SUBJECT STATES HE HAD SURGICAL CONSULT ON 30NOV2020 AND WILL HAVE RADIATION CONSULT ON 03DEC2020, HE WILL THEN DETERMINE THE BEST COURSE OF TREATMENT. HE WAS. UPDATE: RADIATION AND SURGICAL CONSULT COMPLETED AND SUBJECT IS SCHEDULED FOR Prostatectomy 1/27/2021.' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Jan 2021 16:26:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. any additional imaging). Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	22 Jan 2021 16:24:43

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WENT TO UROLOGIST ON 22OCT2020. PROSTATE BIOPSY WAS SCHEDULED DUE TO INCREASING PSA LEVELS OVER LAST SEVERAL YEARS. MEDICAL RECORDS RECEIVED TO REVEAL PROSTATIC ADENOCARCINOMA. PER PI, THIS DOES MEET SERIOUS CRITERIA. WILL FOLLOW SUBJECT FOR PLAN OF TREATMENT. SUBJECT STATES HE HAD SURGICAL CONSULT ON 30NOV2020 AND WILL HAVE RADIATION CONSULT ON 03DEC2020, HE WILL THEN DETERMINE THE BEST COURSE OF TREATMENT. HE WAS. UPDATE: Radiation and surgical consult completed and subject IS SCHEDULED FOR SURGERY 1/27/2021.' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Jan 2021 16:24:35
User entered 'SUBJECT WENT TO UROLOGIST ON 22OCT2020. PROSTATE BIOPSY WAS SCHEDULED DUE TO INCREASING PSA LEVELS OVER LAST SEVERAL YEARS. MEDICAL RECORDS RECEIVED TO REVEAL PROSTATIC ADENOCARCINOMA. PER PI, THIS DOES MEET SERIOUS CRITERIA. WILL FOLLOW SUBJECT FOR PLAN OF TREATMENT. SUBJECT STATES HE HAD SURGICAL CONSULT ON 30NOV2020 AND WILL HAVE RADIATION CONSULT ON 03DEC2020, HE WILL THEN DETERMINE THE BEST COURSE OF TREATMENT. HE WAS. UPDATE: Renal and bladder ultrasound showed enlarged prostate, otherwise normal SUBJECT IS SCHEDULED FOR SURGERY 1/27/2021.' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Jan 2021 16:20:06

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event. 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 'no treatment, other than prostatectomy scheduled 1/27/2021' (Site from Safety). DataPoint Un-verified.	Donna Toepfer (b) (4)	22 Jan 2021 16:16:31
User entered 'SUBJECT WENT TO UROLOGIST ON 22OCT2020. PROSTATE BIOPSY WAS SCHEDULED DUE TO INCREASING PSA LEVELS OVER LAST SEVERAL YEARS. MEDICAL RECORDS RECEIVED TO REVEAL PROSTATIC ADENOCARCINOMA. PER PI, THIS DOES MEET SERIOUS CRITERIA. WILL FOLLOW SUBJECT FOR PLAN OF TREATMENT. SUBJECT STATES HE HAD SURGICAL CONSULT ON 30NOV2020 AND WILL HAVE RADIATION CONSULT ON 03DEC2020, HE WILL THEN DETERMINE THE BEST COURSE OF TREATMENT. HE WAS. Update: Subject is scheduled for surgery 1/27/2021.' reason for change: Data Entry Error DataPoint Verified.	Donna Toepfer (b) (4)	22 Jan 2021 16:15:43
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 04:29:02
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. any additional imaging). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 16:11:24
User closed query 'PV Query: Has the subject seen an oncologist or have plans to see one? If so, what is the course of treatment.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 16:11:18
	(b) (4), (b) (6)	02 Dec 2020 19:16:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

1687 of 1990

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide date of biopsy and consider updating event start to date of biopsy (if not already).' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 19:16:25
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 19:16:16
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. any additional imaging). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 19:16:11
Query 'PV Query: Has the subject seen an oncologist or have plans to see one? If so, what is the course of treatment.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	01 Dec 2020 21:25:53
Query 'PV Query: Please provide treatment given for the event. 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 'treatment is unknown at this time, will decide after consult on 03Dec2020' (Site from Safety).	Donna Toepfer (b) (4)	01 Dec 2020 21:25:45
User entered 'SUBJECT WENT TO UROLOGIST ON 22OCT2020. PROSTATE BIOPSY WAS SCHEDULED DUE TO INCREASING PSA LEVELS OVER LAST SEVERAL YEARS. MEDICAL RECORDS RECEIVED TO REVEAL PROSTATIC ADENOCARCINOMA. PER PI, THIS DOES MEET SERIOUS CRITERIA. WILL FOLLOW SUBJECT FOR PLAN OF TREATMENT. subject states he had surgical consult on 30Nov2020 and will have radiation consult on 03Dec2020, he will then determine the best course of treatment. He was' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Dec 2020 21:25:01
Query 'PV Query: Please provide date of biopsy and consider updating event start to date of biopsy (if not already).' answered with 'date is consistent with biopsy date' (Site from Safety).	Donna Toepfer (b) (4)	01 Dec 2020 16:11:30

PRODUCTION RELEASE (v12.003
EAB) (1725)

1688 of 1990

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. any additional imaging). Please include units and reference ranges if applicable.' answered with 'none rec'd at this time' (Site from Safety). DataPoint Un-verified.	Donna Toepfer (b) (4) [REDACTED] [REDACTED]	01 Dec 2020 16:10:07
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	24 Nov 2020 17:21:02
User opened query 'PV Query: Has the subject seen an oncologist or have plans to see one? If so, what is the course of treatment.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	24 Nov 2020 17:20:55
User opened query 'PV Query: Please provide date of biopsy and consider updating event start to date of biopsy (if not already).' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	23 Nov 2020 18:24:30
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	23 Nov 2020 18:23:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. any additional imaging). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	23 Nov 2020 18:23:30
DataPoint Un-verified.	(b) (4), (b) (6) [REDACTED]	23 Nov 2020 18:22:59
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	19 Nov 2020 20:40:15
User entered 'Subject went to urologist on 22Oct2020. Prostate biopsy was scheduled due to increasing PSA levels over last several years. Medical records received to reveal Prostatic Adenocarcinoma. Per PI, this does meet serious criteria. Will follow subject for plan of treatment'	Donna Toepfer (b) (4) [REDACTED] [REDACTED]	14 Nov 2020 07:26:51
		13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 14:07:42

US3242314

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 14:07:42

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:14:28

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:33:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:04:44

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:06:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:06:45
Data point term sent to Coder	System	10 Sep 2020 16:05:37
User entered 'Lisinopril'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Hypertension'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '40'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'mg (mg)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'UN UNK 1994'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:05:18

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:07:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:07:53
Data point term sent to Coder	System	10 Sep 2020 16:06:39
User entered 'Amlodipine'	Donna Toepfer (b) (4) (b) (4) (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Hypertension'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '5'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'mg (mg)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'UN UNK 1994'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:05:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:07:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:07:54
Data point term sent to Coder	System	10 Sep 2020 16:06:41
User entered 'Levothyroxine'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Hypothyroidism'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '125'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'ug (ug)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Un UNK 2000'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:06:17

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
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)	10 Sep 2020 16:07:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:07:53
Data point term sent to Coder	System	10 Sep 2020 16:06:41
User entered 'Aspirin'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:08:53
DataPoint Un-verified.	Erynn McKinley (b) (4) (b) (4)	22 Dec 2020 17:26:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	22 Dec 2020 17:26:06
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Heart health'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '81'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'mg (mg)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Un Jan 2020'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:06:36

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:08:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:08:42
Data point term sent to Coder	System	10 Sep 2020 16:07:43
User entered 'Zyrtec'	Donna Toepfer (b) (4) (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Seasonal and Perennial allergic rhinitis'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '10'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'mg (mg)'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'UN UNK 2016'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) - (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 16:07:03

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 13:20:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 13:20:29
Data point term sent to Coder	System	14 Oct 2020 13:19:41
User entered 'Acetaminophen'	Grace Newville (b) (4) (b) (4)	14 Oct 2020 13:19:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the CHILLS / BODY ACHES 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 of 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 CHILLS / BODY ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:37:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the CHILLS / BODY ACHES 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 of 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 CHILLS / BODY ACHES did not meet the AE reporting criteria.' answered with 'captured in subject's diary' (Site from DM).	Donna Toepfer (b) (4)	23 Nov 2020 17:22:46

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the CHILLS / BODY ACHES 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 of 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 CHILLS / BODY ACHES did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 10:30:50
	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Chills / Body aches'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '1000'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'mg (mg)'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'once (ONCE)'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Oral (ORAL)'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '10 Oct 2020'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '0'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '10 Oct 2020'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Grace Newville (b) (4)	14 Oct 2020 13:19:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 13:19:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 13:19:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:19
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 13:19:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening BENIGN PROSTATIC HYPERPLASIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 16:15:46
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening BENIGN PROSTATIC HYPERPLASIA should be recorded, and update con med indication or provide clarification. ' answered with 'he had bph, but wasnt being treated for it, not a worsening' (Site from DM).	Donna Toepfer (b) (4)	09 Dec 2020 15:14:38
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening BENIGN PROSTATIC HYPERPLASIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 19:49:01
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: ALFUZOSIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:46:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:46:31
Data point term sent to Coder	System	05 Nov 2020 22:45:32

PRODUCTION RELEASE (v12.003
EAB) (1725)

1802 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Alfuzosin'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:45:27

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Benign prostatic hyperplasia'	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '10'	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'mg (mg)'	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'once daily (QD)'	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '31 Oct 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '0'	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Feb 2021 20:22:35
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Feb 2021 20:22:35
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:45:27

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Feb 2021 20:22:35
User entered '27 Jan 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Feb 2021 20:22:35
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:45:27

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:45:27
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User entered '1'	(b) (4), (b) (6) System	05 Nov 2020 22:45:27

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User entered '1'	(b) (4), (b) (6) System	05 Nov 2020 22:45:27

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User entered '804 (804)'	(b) (4), (b) (6) System	05 Nov 2020 22:45:27

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:23:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:23:30
Data point term sent to Coder	System	05 Nov 2020 22:46:36
User entered 'Ciprofloxacin'	Erynn McKinley (b) (4) (b) (4)	05 Nov 2020 22:46:30

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Prophylaxis for prostate biopsy'	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '500'	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'mg (mg)'	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'twice daily (BID)'	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '2 Nov 2020'	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '0'	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User closed query 'Per DM CLR: Per DM CLR: Please verify if a stop date should be recorded for this Con Med as it is not typically used to treat so long this condition. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 16:16:13
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
Query 'Per DM CLR: Per DM CLR: Please verify if a stop date should be recorded for this Con Med as it is not typically used to treat so long this condition. If yes, please update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	09 Dec 2020 16:07:46
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Dec 2020 16:07:40
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	09 Dec 2020 16:07:40
User opened query 'Per DM CLR: Per DM CLR: Please verify if a stop date should be recorded for this Con Med as it is not typically used to treat so long this condition. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	18 Dec 2020 04:29:02
DataPoint Un-verified.	Donna Toepfer (b) (4)	09 Dec 2020 16:07:40
User entered '11 Nov 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	09 Dec 2020 16:07:40
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'No (N)'	Erynn McKinley (b) (4)	05 Nov 2020 22:46:30
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
User entered '2'	(b) (4), (b) (6) System	05 Nov 2020 22:46:30

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
User entered '1'	(b) (4), (b) (6) System	05 Nov 2020 22:46:30

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:56
User entered '804 (804)'	(b) (4), (b) (6) System	05 Nov 2020 22:46:30

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 08:59:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 08:59:44
Data point term sent to Coder	System	08 Feb 2021 15:49:04
Coding entries removed.	Donna Toepfer (b) (4)	08 Feb 2021 15:48:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 12:35:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 12:35:07
Data point term sent to Coder	System	03 Feb 2021 19:46:47
User entered 'Docusate Sodium'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Post PROCEDURE, PROSTATECTOMY' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Feb 2021 15:48:18
User entered 'Procedure, Prostatectomy'	Erynn McKinley (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '100'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'twice daily (BID)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '28 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:29:01
Signature has been broken.	Donna Toepfer (b) (4)	08 Mar 2021 15:37:31
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Mar 2021 15:37:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:29:01
Signature has been broken.	Donna Toepfer (b) (4)	08 Mar 2021 15:37:31
User entered '28 Feb 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Mar 2021 15:37:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
User entered '2'	(b) (4), (b) (6) System	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
User entered '1'	(b) (4), (b) (6) System	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:52:37
User entered '804 (804)'	(b) (4), (b) (6) System	03 Feb 2021 19:46:47

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:37:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:37:50
Data point term sent to Coder	System	10 Mar 2021 00:05:22
Coding entries removed.	Donna Toepfer (b) (4)	10 Mar 2021 00:05:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 00:49:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 00:49:43
Data point term sent to Coder	System	08 Feb 2021 15:49:04
Coding entries removed.	Donna Toepfer (b) (4)	08 Feb 2021 15:48:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 10:36:43

PRODUCTION RELEASE (v12.003
EAB) (1725)

1857 of 1990

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Feb 2021 10:36:43
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	03 Feb 2021 19:49:53
User entered 'Ciprofloxacin'	Erynn McKinley (b) (4)	03 Feb 2021 19:49:26
	(b) (4)	

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:29:01
User closed query 'Per DM CLR: Please update the indication of this medication to reflect the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 09:40:32
Query 'Per DM CLR: Please update the indication of this medication to reflect the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	10 Mar 2021 00:05:15
Signature has been broken.	Donna Toepfer (b) (4)	10 Mar 2021 00:05:06
User entered 'POST PROCEDURE, Prophylaxis for infection' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Mar 2021 00:05:06
User opened query 'Per DM CLR: Please update the indication of this medication to reflect the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 23:30:06
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Post PROCEDURE, PROSTATECTOMY' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Feb 2021 15:48:32
User entered 'Procedure, Prostatectomy'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '500'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'twice daily (BID)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '3 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '0'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Feb 2021 15:48:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Feb 2021 20:26:22
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Feb 2021 20:23:19
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '05 Feb 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Feb 2021 15:48:44
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 20:26:22
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	03 Feb 2021 20:26:22
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	03 Feb 2021 20:23:19
User entered '05 Feb 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Feb 2021 20:23:19
User entered empty.	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 19:45:10
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
User entered '2'	(b) (4), (b) (6) System	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
User entered '1'	(b) (4), (b) (6) System	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:14:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:59
User entered '804 (804)'	(b) (4), (b) (6) System	03 Feb 2021 19:49:26

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:14:28

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:33:31
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Nov 2020 14:00:24
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 16:07:12

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:28

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered '04 Nov 2020'	Donna Toepfer (b) (4)	13 Nov 2020 14:01:03

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Prostate Biopsy'	Donna Toepfer (b) (4) (b) (4)	13 Nov 2020 14:01:03

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4) (b) (4)	13 Nov 2020 14:01:03

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:14:28

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 07:28:34
User entered empty.	Donna Toepfer (b) (4)	13 Nov 2020 14:01:03

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:14:28

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered '27 Jan 2021'	Donna Toepfer (b) (4)	08 Feb 2021 15:42:24

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:14:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Prostatectomy'	Donna Toepfer (b) (4)	08 Feb 2021 15:42:24

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:14:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:28
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:57:52
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	01 Mar 2021 22:04:24
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:04:26
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4)	08 Feb 2021 15:42:24

US3242314

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:14:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:16:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:45:28
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
User entered empty.	Donna Toepfer (b) (4)	08 Feb 2021 15:42:24

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'USA-US067-2020-MRNA-1273-P301000012'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Nathan'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Segall'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '175 country club dr st100a'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Stockbridge'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:04:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 14:29:48
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:29:03
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 12:37:02
Signature has been broken.	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:49
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:14
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
User entered empty.	System	08 Apr 2021 13:17:45
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	08 Apr 2021 12:29:14
User entered 'GA'	Donna Toepfer (b) (4)	08 Apr 2021 12:28:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:46:37

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:08:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '30281'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:08:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
User entered 'US'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 13:17:45
User entered '4'	System	02 Mar 2021 16:32:48
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4)	
User entered '3'	System	25 Jan 2021 02:19:23
User entered '2'	System	02 Dec 2020 18:09:05
User entered '1'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'USA-US067-2020-MRNA-1273-P301000012'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Nathan'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Segall'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '175 country club dr st100a'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Stockbridge'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE-USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:04:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 14:29:48
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:29:03
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 12:37:02
Signature has been broken.	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:49
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:14
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
User entered empty.	System	08 Apr 2021 13:17:45
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	08 Apr 2021 12:29:14
User entered 'GA'	Donna Toepfer (b) (4)	08 Apr 2021 12:28:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:46:37

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:08:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '30281'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:08:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
User entered 'US'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 13:17:45
User entered '4'	System	02 Mar 2021 16:32:48
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4)	
User entered '3'	System	25 Jan 2021 02:19:23
User entered '2'	System	02 Dec 2020 18:09:05
User entered '1'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:14:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
User entered '16/Nov/2020 20:23'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:14:28

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.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:08:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered	(b) (4), (b) (6)	16 Nov 2020 20:22:34
'USA-US067-2020-MRNA-1273-P301000012'	System	

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Nathan'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Segall'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '175 country club dr st100a'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Stockbridge'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE-USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:04:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 14:29:48
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:29:03
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 12:37:02
Signature has been broken.	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:49
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:14
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
User entered empty.	System	08 Apr 2021 13:17:45
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	08 Apr 2021 12:29:14
User entered 'GA'	Donna Toepfer (b) (4)	08 Apr 2021 12:28:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:46:37

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:08:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '30281'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:08:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
User entered 'US'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 13:17:45
User entered '4'	System	02 Mar 2021 16:32:48
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4)	
User entered '3'	System	25 Jan 2021 02:19:23
User entered '2'	System	02 Dec 2020 18:09:05
User entered '1'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:14:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:07:57
User entered '02/Dec/2020 13:09'	System	02 Dec 2020 18:09:05

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:14:28

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.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:07:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:19:13
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 18:09:05

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'USA-US067-2020-MRNA-1273-P301000012'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Nathan'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Segall'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '175 country club dr st100a'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Stockbridge'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE-USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:04:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 14:29:48
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:29:03
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 12:37:02
Signature has been broken.	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:49
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:14
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
User entered empty.	System	08 Apr 2021 13:17:45
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	08 Apr 2021 12:29:14
User entered 'GA'	Donna Toepfer (b) (4)	08 Apr 2021 12:28:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:46:37

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:08:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '30281'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:08:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
User entered 'US'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 13:17:45
User entered '4'	System	02 Mar 2021 16:32:48
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4)	
User entered '3'	System	25 Jan 2021 02:19:23
User entered '2'	System	02 Dec 2020 18:09:05
User entered '1'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:14:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:07:57
User entered '24/Jan/2021 21:19'	System	25 Jan 2021 02:19:23

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:14:28

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:32:37
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:07:57
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 02:19:23

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered	(b) (4), (b) (6)	16 Nov 2020 20:22:34
'USA-US067-2020-MRNA-1273-P301000012'	System	

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Nathan'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Segall'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '175 country club dr st100a'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Stockbridge'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE-USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:04:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 14:29:48
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:29:03
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 12:37:02
Signature has been broken.	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:49
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:14
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
User entered empty.	System	08 Apr 2021 13:17:45
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	08 Apr 2021 12:29:14
User entered 'GA'	Donna Toepfer (b) (4)	08 Apr 2021 12:28:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:46:37

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:08:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '30281'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:08:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
User entered 'US'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 13:17:45
User entered '4'	System	02 Mar 2021 16:32:48
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4)	
User entered '3'	System	25 Jan 2021 02:19:23
User entered '2'	System	02 Dec 2020 18:09:05
User entered '1'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:14:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:58:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '02/Mar/2021 11:32'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:14:28

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)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:58:07
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered	(b) (4), (b) (6)	16 Nov 2020 20:22:34
'USA-US067-2020-MRNA-1273-P301000012'	System	

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'Yes (Y)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 20:23:05
User entered 'No (N)'	System	16 Nov 2020 20:22:34

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:56
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Nathan'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Segall'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '175 country club dr st100a'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:07:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered 'Stockbridge'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE-USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:04:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 14:29:48
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 14:29:03
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 12:37:02
Signature has been broken.	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Apr 2021 12:36:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:49
User closed query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:06:14
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
User entered empty.	System	08 Apr 2021 13:17:45
Query 'Please enter the state in site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	08 Apr 2021 12:29:14
User entered 'GA'	Donna Toepfer (b) (4)	08 Apr 2021 12:28:47
User opened query 'Please enter the state in site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:46:37

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 00:08:17
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:09:47
User entered '30281'	System	02 Mar 2021 16:32:48

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	12 Feb 2021 18:41:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:08:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:19:19
User entered 'US'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 13:17:45
User entered '4'	System	02 Mar 2021 16:32:48
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:41:15
	(b) (4)	
User entered '3'	System	25 Jan 2021 02:19:23
User entered '2'	System	02 Dec 2020 18:09:05
User entered '1'	System	16 Nov 2020 20:23:38

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:14:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:58:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 21:18:31
User entered '08/Apr/2021 06:17'	System	08 Apr 2021 13:17:45

US3242314

Folder: SAE USA-US067-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:14:28

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)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:58:07
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 21:18:31
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 13:17:45