

US3492243 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3492243

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 04:17:55

Generated On: 10 Jun 2021 08:01:25

Participant ID

US3492243

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

US3492243

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3492243

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3492243

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Date of Informed Consent (<i>dd MMM yyyy</i>)	23 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

US3492243

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3492243

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Were any significant conditions reported?

Yes ☐

No ☒

US3492243

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:53 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 09:53
Height (<i>xxx.x</i>)	181.5 cm
Weight (<i>xxx.x</i>)	113.4 kg
BMI (<i>xxx.x</i>)	34.42388 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	ND - Not Done
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)	

US3492243

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3492243

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

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 IT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3492243

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3492243

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

What was the date of randomization? (dd MMM yyyy) 23 SEP 2020

What was the participant's randomization number? 115300

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 ☒

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Height	ND - Not Done
Weight	ND - Not Done

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

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)	23 SEP 2020
Time of assessment (00:00-23:59)	09:53 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 09:53
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	11:09 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 11:09
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3492243

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 11:03 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 11:03

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

US3492243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	10:27 (24 HR)
Collection date and time (derived)	23 SEP 2020 10:27

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	23 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

US3492243

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 11:24

PC Open Date & Time

23 SEP 2020 11:23

PC Close Date & Time

23 SEP 2020 13:53

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	23 SEP 2020 17:51
PC Open Date & Time	23 SEP 2020 14:48
PC Close Date & Time	24 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

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):

PC Time Stamp

24 SEP 2020 12:09

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

25 SEP 2020 14:21

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

97.9 °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

26 SEP 2020 21:28

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 14:48

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

28 SEP 2020 12:44

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

29 SEP 2020 12:15

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 11:25

PC Open Date & Time

23 SEP 2020 11:23

PC Close Date & Time

23 SEP 2020 13:53

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

23 SEP 2020 17:51

PC Open Date & Time

23 SEP 2020 14:48

PC Close Date & Time

24 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

24 SEP 2020 12:10

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

25 SEP 2020 14:21

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

26 SEP 2020 21:28

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

27 SEP 2020 14:48

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

28 SEP 2020 12:44

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

29 SEP 2020 12:15

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 11:26
PC Open Date & Time	23 SEP 2020 11:23
PC Close Date & Time	23 SEP 2020 13:53

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 17:52
PC Open Date & Time	23 SEP 2020 14:48
PC Close Date & Time	24 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

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 ☒

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

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 ☒

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 14:21
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

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 ☒

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 21:29
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

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 ☒

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 14:49
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

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 ☒

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 12:44
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

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 ☒

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:15
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3492243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492243

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:58

Generated On: 10 Jun 2021 08:01:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3492243

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:58

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:58

Generated On: 10 Jun 2021 08:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492243

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:58

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	09:23 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 09:23
Temperature (xxx.x)	36 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
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)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	10:42 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 10:42
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3492243

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 OCT 2020

What was the treatment time? (00:00-23:59) 10:35 (24 HR)

Treatment Date and Time (derived) 21 OCT 2020 10:35

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

What was the frequency of the study treatment dosing? ONCE

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

US3492243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3492243

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 10:55

PC Open Date & Time

21 OCT 2020 10:55

PC Close Date & Time

21 OCT 2020 13:25

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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	22 OCT 2020 04:28
PC Open Date & Time	21 OCT 2020 14:20
PC Close Date & Time	22 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 12:01

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 10:22

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 12:00

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 11:30

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 10:45

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 OCT 2020 07:15

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 10:55

PC Open Date & Time

21 OCT 2020 10:55

PC Close Date & Time

21 OCT 2020 13:25

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

22 OCT 2020 04:28

PC Open Date & Time

21 OCT 2020 14:20

PC Close Date & Time

22 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

22 OCT 2020 12:01

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

24 OCT 2020 10:21

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

24 OCT 2020 12:01

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

26 OCT 2020 11:30

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

27 OCT 2020 10:45

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

28 OCT 2020 07:16

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 10:56
PC Open Date & Time	21 OCT 2020 10:55
PC Close Date & Time	21 OCT 2020 13:25

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 04:29
PC Open Date & Time	21 OCT 2020 14:20
PC Close Date & Time	22 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

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 ☒

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 12:02
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

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)

89 of 2521

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 10:23
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

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 ☒

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 12:01
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

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 ☒

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 11:31
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

95 of 2521

EAB) (1725)

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 10:46
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

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 ☒

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 07:16
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 28 OCT 2020 14:32

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

30 OCT 2020 09:35

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

30 OCT 2020 13:55

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

31 OCT 2020 12:07

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 NOV 2020 23:59

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

02 NOV 2020 12:50

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

03 NOV 2020 12:00

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

04 NOV 2020 12:00

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 06 NOV 2020 15:30

PC Open Date & Time 06 NOV 2020 12:00

PC Close Date & Time 07 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 OCT 2020 14:32
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 OCT 2020 09:35
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 OCT 2020 13:56
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 OCT 2020 12:07
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 NOV 2020 23:59
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

02 NOV 2020 12:50

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 NOV 2020 12:01
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 NOV 2020 12:00
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 NOV 2020 15:30
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3492243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:58

Generated On: 10 Jun 2021 08:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492243

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:58

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492243

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:18:16

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3492243

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:53:57

Generated On: 10 Jun 2021 08:01:25

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT3

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 01:53:58

Generated On: 10 Jun 2021 08:01:25

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) _____

US3492243

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:53:57

Generated On: 10 Jun 2021 08:01:25

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.

US3492243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 01:53:57

Generated On: 10 Jun 2021 08:01:25

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3492243

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 61
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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 18:21:52
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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	08 DEC 2020 19:31:43
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

13 DEC 2020 12:16:40

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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	18 DEC 2020 07:42:27
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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	25 DEC 2020 08:03:27
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

01 JAN 2021 00:02:40

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 07:16:53
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

17 JAN 2021 12:13:40

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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	22 JAN 2021 01:22:36
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

31 JAN 2021 12:57:56

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 16:45:48
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 07:09:08
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 07:10:46
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 12:02:56

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

05 MAR 2021 06:28:08

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

19 MAR 2021 07:15:50

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

26 MAR 2021 06:11:02

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 07:00:24
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

09 APR 2021 03:49:40

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

19 APR 2021 17:59:29

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

23 APR 2021 07:31:26

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 12:00:30

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 <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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 <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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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="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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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="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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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="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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 <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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 <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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 <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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 <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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 <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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

Patient Cloud Close Date & Time	11 OCT 2022 23:59
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US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 <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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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"/>

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

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

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3492243

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:01:25

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		28 FEB 2021 12:03:09

US3492243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492243

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:18:17

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:17:58

Generated On: 10 Jun 2021 08:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492243

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:17:58

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:53:57

Generated On: 10 Jun 2021 08:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492243

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:53:57

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:53:57

Generated On: 10 Jun 2021 08:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492243

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:53:57

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:32:42

Generated On: 10 Jun 2021 08:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:32:42

Generated On: 10 Jun 2021 08:01:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 APR 2021
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	20 APR 2021 09:20
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:32:42

Generated On: 10 Jun 2021 08:01:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 APR 2021

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

US3492243

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:32:42

Generated On: 10 Jun 2021 08:01:25

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

Collection date (dd MMM yyyy)	20 APR 2021
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Collection time (00:00-23:59)	09:19 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	20 APR 2021 09:19
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US3492243

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 16:32:42

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Date of Contact	18 NOV 2020
Time of Contact	09:45
Date and Time of Contact (derived)	18 NOV 2020 09:45
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<hr/>	
O2 Saturation Units	<hr/>	
Temperature	<hr/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

342 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	9 NOV 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

346 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

355 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

358 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

370 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

374 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

375 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	98.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

382 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

386 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

390 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

394 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

395 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

398 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Symptom Day

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

402 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 16:32:41

Generated On: 10 Jun 2021 08:01:25

Date of Visit	18 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	11 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input checked="" type="radio"/>
Other, specify	OROPHARYNGEAL
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	NORTHSHORE IMMEDIATE CARE CENTER
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 03:53:14

Generated On: 10 Jun 2021 08:01:25

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 03:53:14

Generated On: 10 Jun 2021 08:01:25

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

407 of 2521

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 03:53:14

Generated On: 10 Jun 2021 08:01:25

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 NOV 2020
Day 5	Yes	22 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3492243

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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	SICKD1

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 NOV 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 10:00
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492243

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3492243

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 NOV 2020

US3492243

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:17:58

Generated On: 10 Jun 2021 08:01:25

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

Visit date (dd MMM yyyy)	28 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3492243

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:53:55

Generated On: 10 Jun 2021 08:01:25

Date of updated informed consent (*dd MMM yyyy*) 28 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*) 28 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 _____

US3492243

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:17:58

Generated On: 10 Jun 2021 08:01:25

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

Collection date (dd MMM yyyy)	28 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	09:33 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	28 JAN 2021 09:33
------------------------------------	-------------------

US3492243

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 04:17:57

Generated On: 10 Jun 2021 08:01:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	09:28
Collection Date and Time (derived)	28 JAN 2021 09:28

US3492243

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

419 of 2521

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

AEID	
Adverse event	MUSCLE ACHES
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	1 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	3 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

421 of 2521

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

AEID

Adverse event

MUSCLE SORENESS AFTER
WORKOUT

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

423 of 2521

EAB) (1725)

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

424 of 2521

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

AEID	USA-US101-2020-MRNA-1273-P30 1000005
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	07 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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)

425 of 2521

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

COVID EXPOSURE FROM
POSITIVE FAMILY MEMBER,
BEGAN QUARANTINE
06NOV2020 C/O FATIGUE 07NOV
TO 08NOV. TOOK OP COVID
TEST AT OUTSIDE FACILITY
11NOV2020, POSITIVE RESULT
13NOV2020. CURRENTLY
ASYMPTOMATIC AT D57 VISIT
BUT CHANGED TO ILLNESS
VISIT DUE TO POSITIVE
RESULT.

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)	

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	22 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

428 of 2521

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 21:45:25

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 01:53:55

Generated On: 10 Jun 2021 08:01:25

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

Yes ☒

No ☐

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

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:32:41

Generated On: 10 Jun 2021 08:01:25

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE AND INJECTION
SITE PAIN

Dose per administration 400

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)

431 of 2521

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:32:41

Generated On: 10 Jun 2021 08:01:25

	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)		21 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)		22 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"/>

US3492243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3492243

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 15 Feb 2021 04:17:56

Generated On: 10 Jun 2021 08:01:25

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

US3492243

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:01:25

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 ☐

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 16:32:41

Generated On: 10 Jun 2021 08:01:25

SAEID	USA-US101-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 16:32:41

Generated On: 10 Jun 2021 08:01:25

SAEID	USA-US101-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/NOV/2020 16:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 16:32:41

Generated On: 10 Jun 2021 08:01:25

SAEID	USA-US101-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	01/DEC/2020 17:41
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

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 16:32:41

Generated On: 10 Jun 2021 08:01:25

SAEID	USA-US101-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/JAN/2021 11:40
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

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 16:32:41

Generated On: 10 Jun 2021 08:01:25

SAEID	USA-US101-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	01/FEB/2021 14:34
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

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 16:32:41

Generated On: 10 Jun 2021 08:01:25

SAEID	USA-US101-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/MAR/2021 10:59
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

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 16:32:41

Generated On: 10 Jun 2021 08:01:25

SAEID	USA-US101-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/APR/2021 16:07
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

US3492243 (Prod: UIC Project WISH CRS)

US3492243

Form: Participant Creation

Generated On: 10 Jun 2021 08:01:25

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'US3492243'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:35:04

US3492243

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	23 Sep 2020 15:24:51

US3492243

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:35:05

US3492243

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Clinic (Clinic)'	Nusirat Williams (b) (4)	23 Sep 2020 15:24:51

US3492243

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered 'SCRN'	System	23 Sep 2020 15:24:51

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered (b) (6) 1970'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:35:07

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '50'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered 'YEARS'	System	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered '50'	System	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Male (M)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'I'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:25

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:25

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 Sep 2020'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered 'Sep 2020'	System	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered '2020'	System	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:25

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Amendment 3 (3)'	Nusirat Williams (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:25

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 14:35:05

US3492243

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered 'I'	System	23 Sep 2020 15:26:13

US3492243

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	23 Sep 2020 15:26:13

US3492243

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:01:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:26:52

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 Sep 2020'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '09:53'	Nusirat Williams (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered '23 Sep 2020 09:53'	System	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '181.5' cm	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:27:48
DataPoint set to visible.	(b) (4) System	23 Sep 2020 15:26:13

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '113.4' kg	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:27:48
DataPoint set to visible.	(b) (4) System	23 Sep 2020 15:26:13

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered '34.42388'	System	23 Sep 2020 15:27:48
DataPoint set to visible.	System	23 Sep 2020 15:26:13

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered 'kg/m2'	System	23 Sep 2020 15:27:48
DataPoint set to visible.	System	23 Sep 2020 15:26:13

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User closed query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 13:07:44
Query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' answered with '-----corrected-----' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:43:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 19:43:17
User opened query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 18:37:41
User entered 'Other (Other)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	Nusirat Williams (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered 'bpm'	System	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered 'breaths/min'	System	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered 'mmHg'	System	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User entered 'mmHg'	System	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44

US3492243

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:27:56

US3492243

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 Sep 2020'	Nusirat Williams (b) (4)	23 Sep 2020 15:27:56

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

[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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

[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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

[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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'IT'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'I'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

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 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:09:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:28:49

US3492243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 Sep 2020'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:28:49

US3492243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[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 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Clinic (Clinic)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:28:49

US3492243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'VISIT1'	System	23 Sep 2020 15:28:49

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 15:09:29

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:25

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '115300'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 15:09:29

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:25

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 15:09:29

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:25

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 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:29:35

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:25

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 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:29:35

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:25

[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:29:35

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:25

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:29:35

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:29:35

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:25

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:29:35
DataPoint set to visible.	(b) (4) System	23 Sep 2020 15:26:07

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User accepted default value 'Pre-Dose (PREDOSE)'	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58
	(b) (4)	

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 Sep 2020'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '09:53'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '23 Sep 2020 09:53'	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '36.4' C	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Other (Other)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'ear'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '58'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'bpm'	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '12'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'breaths/min'	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '161'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'mmHg'	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '94'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'mmHg'	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered missing code ND - Not Done.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User accepted default value 'Post-Dose (POSTDOSE)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 16:14:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Sep 2020 15:30:58
	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58
	(b) (4)	

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 Sep 2020' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '11:09' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '23 Sep 2020 11:09'	System	23 Sep 2020 16:14:17
User entered empty.	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '36.3' C reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Other (Other)' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Tympanic' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '58' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'bpm'	System	23 Sep 2020 16:14:17
User entered empty.	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '15' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'breaths/min'	System	23 Sep 2020 16:14:17
User entered empty.	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '121' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'mmHg'	System	23 Sep 2020 16:14:17
User entered empty.	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '77' reason for change: Data Entry Error	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
User entered empty.	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'mmHg'	System	23 Sep 2020 16:14:17
User entered empty.	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:31:08

US3492243

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 Sep 2020'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:31:08

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	Gizelle Alvarez (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

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 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	Gizelle Alvarez (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 Sep 2020'	Gizelle Alvarez (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '11:03'	(b) (4) Gizelle Alvarez (b) (4) (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '23 Sep 2020 11:03'	System	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Right Arm (RIGHT ARM)'	Gizelle Alvarez (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'ONCE'	System	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:31:29

US3492243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 Sep 2020'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:31:29

US3492243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '10:27'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:31:29

US3492243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '23 Sep 2020 10:27'	System	23 Sep 2020 15:31:29

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '23 Sep 2020'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nusirat Williams (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '10:30'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '23 Sep 2020 10:30'	System	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nusirat Williams (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:25

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered empty.	System	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:31:54

US3492243

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '1'	System	23 Sep 2020 15:31:54

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:23:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dd77daf8-8e54-43e2-92e8-3c2c51215635'	System	23 Sep 2020 16:24:34
User entered 'Yes (Y)'	System	23 Sep 2020 16:24:34

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:24:17', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dd77daf8-8e54-43e2-92e8-3c2c51215635' User entered '97.3'	System	23 Sep 2020 16:24:34
	System	23 Sep 2020 16:24:34

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:24:27', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dd77daf8-8e54-43e2-92e8-3c2c51215635'	System	23 Sep 2020 16:24:34
User entered 'No (N)'	System	23 Sep 2020 16:24:34

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:24:31', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dd77daf8-8e54-43e2-92e8-3c2c51215635' User entered '23 Sep 2020 11:24'	System	23 Sep 2020 16:24:34
	System	23 Sep 2020 16:24:34

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Sep 2020 11:23'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Sep 2020 13:53'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:49:33', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0125d593-183c-4b0b-8884-dfd633931a7b' User entered 'Yes (Y)'	System	23 Sep 2020 22:51:11
	System	23 Sep 2020 22:51:11

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:01', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0125d593-183c-4b0b-8884-dfd633931a7b' User entered '98.4'	System	23 Sep 2020 22:51:11
	System	23 Sep 2020 22:51:11

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:06', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0125d593-183c-4b0b-8884-dfd633931a7b' User entered 'No (N)'	System	23 Sep 2020 22:51:11
	System	23 Sep 2020 22:51:11

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:09', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0125d593-183c-4b0b-8884-dfd633931a7b' User entered '23 Sep 2020 17:51'	System	23 Sep 2020 22:51:11
	System	23 Sep 2020 22:51:11

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Sep 2020 14:48'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 2'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:08:45', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'bcaace36-3d81-4126-81cc-380daaa48c76' User entered 'Yes (Y)'	System	24 Sep 2020 17:09:48
	System	24 Sep 2020 17:09:48

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:09:24', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'bcaace36-3d81-4126-81cc-380daaa48c76' User entered '98.6'	System	24 Sep 2020 17:09:48
	System	24 Sep 2020 17:09:48

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:09:39', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'bcaace36-3d81-4126-81cc-380daaa48c76'	System	24 Sep 2020 17:09:48
User entered 'No (N)'	System	24 Sep 2020 17:09:48

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:09:46', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'bcaace36-3d81-4126-81cc-380daaa48c76' User entered '24 Sep 2020 12:09'	System	24 Sep 2020 17:09:48
	System	24 Sep 2020 17:09:48

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 3'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:19:56', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ba079b91-90eb-4231-867b-1c8234d13b99'	System	25 Sep 2020 19:21:09
User entered 'Yes (Y)'	System	25 Sep 2020 19:21:09

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:20:57', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ba079b91-90eb-4231-867b-1c8234d13b99'	System	25 Sep 2020 19:21:09
User entered '98.5'	System	25 Sep 2020 19:21:09

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:02', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ba079b91-90eb-4231-867b-1c8234d13b99'	System	25 Sep 2020 19:21:09
User entered 'No (N)'	System	25 Sep 2020 19:21:09

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:05', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ba079b91-90eb-4231-867b-1c8234d13b99'	System	25 Sep 2020 19:21:09
User entered '25 Sep 2020 14:21'	System	25 Sep 2020 19:21:09

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 4'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:26:45', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '66befc5b-1ab8-4522-b32d-db2e88b25edf' User entered 'Yes (Y)'	System	27 Sep 2020 02:28:27
	System	27 Sep 2020 02:28:27

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:18', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '66befc5b-1ab8-4522-b32d-db2e88b25edf' User entered '97.9'	System	27 Sep 2020 02:28:27
	System	27 Sep 2020 02:28:27

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:23', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '66befc5b-1ab8-4522-b32d-db2e88b25edf' User entered 'No (N)'	System	27 Sep 2020 02:28:27
	System	27 Sep 2020 02:28:27

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:25', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '66befc5b-1ab8-4522-b32d-db2e88b25edf' User entered '26 Sep 2020 21:28'	System	27 Sep 2020 02:28:27
	System	27 Sep 2020 02:28:27

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 5'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:48:33', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '24aa4fe4-7681-4954-ad5b-221981b01655' User entered 'Yes (Y)'	System	27 Sep 2020 19:48:47
	System	27 Sep 2020 19:48:47

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:48:38', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '24aa4fe4-7681-4954-ad5b-221981b01655' User entered '98.3'	System	27 Sep 2020 19:48:47
	System	27 Sep 2020 19:48:47

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:48:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '24aa4fe4-7681-4954-ad5b-221981b01655'	System	27 Sep 2020 19:48:47
User entered 'No (N)'	System	27 Sep 2020 19:48:47

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:48:44', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '24aa4fe4-7681-4954-ad5b-221981b01655'	System	27 Sep 2020 19:48:47
User entered '27 Sep 2020 14:48'	System	27 Sep 2020 19:48:47

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 6'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0315b931-4ea8-4eeb-bd03-716ac2127fd5' User entered 'Yes (Y)'	System	28 Sep 2020 17:44:17
	System	28 Sep 2020 17:44:17

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:08', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0315b931-4ea8-4eeb-bd03-716ac2127fd5' User entered '98.4'	System	28 Sep 2020 17:44:17
	System	28 Sep 2020 17:44:17

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:12', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0315b931-4ea8-4eeb-bd03-716ac2127fd5'	System	28 Sep 2020 17:44:17
User entered 'No (N)'	System	28 Sep 2020 17:44:17

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:14', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0315b931-4ea8-4eeb-bd03-716ac2127fd5' User entered '28 Sep 2020 12:44'	System	28 Sep 2020 17:44:17
	System	28 Sep 2020 17:44:17

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 7'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:14:35', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3cc73b53-e8fe-4229-9289-bfa17aa4e02a' User entered 'Yes (Y)'	System	29 Sep 2020 17:15:07
	System	29 Sep 2020 17:15:07

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:14:57', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3cc73b53-e8fe-4229-9289-bfa17aa4e02a' User entered '98.4'	System	29 Sep 2020 17:15:07
	System	29 Sep 2020 17:15:07

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:01', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3cc73b53-e8fe-4229-9289-bfa17aa4e02a'	System	29 Sep 2020 17:15:07
User entered 'No (N)'	System	29 Sep 2020 17:15:07

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:03', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3cc73b53-e8fe-4229-9289-bfa17aa4e02a' User entered '29 Sep 2020 12:15'	System	29 Sep 2020 17:15:07
	System	29 Sep 2020 17:15:07

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:24:51', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8f61e7e7-e499-4145-8145-2af4332f9f68'	System	23 Sep 2020 16:25:44
User entered 'None (1)'	System	23 Sep 2020 16:25:44

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:25:13', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8f61e7e7-e499-4145-8145-2af4332f9f68'	System	23 Sep 2020 16:25:44
User entered 'No (N)'	System	23 Sep 2020 16:25:44

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:25:23', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8f61e7e7-e499-4145-8145-2af4332f9f68' User entered 'No (N)'	System	23 Sep 2020 16:25:44
	System	23 Sep 2020 16:25:44

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:25:35', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8f61e7e7-e499-4145-8145-2af4332f9f68'	System	23 Sep 2020 16:25:44
User entered 'None (1)'	System	23 Sep 2020 16:25:44

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:25:39', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8f61e7e7-e499-4145-8145-2af4332f9f68'	System	23 Sep 2020 16:25:44
User entered '23 Sep 2020 11:25'	System	23 Sep 2020 16:25:44

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Sep 2020 11:23'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Sep 2020 13:53'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:15', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '506fd5a5-4755-42db-87ed-e83476e14d97'	System	23 Sep 2020 22:51:32
User entered 'None (1)'	System	23 Sep 2020 22:51:32

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:19', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '506fd5a5-4755-42db-87ed-e83476e14d97'	System	23 Sep 2020 22:51:32
User entered 'No (N)'	System	23 Sep 2020 22:51:32

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:23', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '506fd5a5-4755-42db-87ed-e83476e14d97' User entered 'No (N)'	System	23 Sep 2020 22:51:32
	System	23 Sep 2020 22:51:32

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:27', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '506fd5a5-4755-42db-87ed-e83476e14d97'	System	23 Sep 2020 22:51:32
User entered 'None (1)'	System	23 Sep 2020 22:51:32

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:29', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '506fd5a5-4755-42db-87ed-e83476e14d97' User entered '23 Sep 2020 17:51'	System	23 Sep 2020 22:51:32
	System	23 Sep 2020 22:51:32

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Sep 2020 14:48'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 2'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:10:15', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3e6a9629-b828-451e-96eb-a5828e87127d'	System	24 Sep 2020 17:10:31
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	24 Sep 2020 17:10:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:10:18', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3e6a9629-b828-451e-96eb-a5828e87127d' User entered 'No (N)'	System	24 Sep 2020 17:10:31
	System	24 Sep 2020 17:10:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:10:21', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3e6a9629-b828-451e-96eb-a5828e87127d' User entered 'No (N)'	System	24 Sep 2020 17:10:31
	System	24 Sep 2020 17:10:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:10:27', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3e6a9629-b828-451e-96eb-a5828e87127d' User entered 'None (1)'	System	24 Sep 2020 17:10:31
	System	24 Sep 2020 17:10:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:10:29', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3e6a9629-b828-451e-96eb-a5828e87127d' User entered '24 Sep 2020 12:10'	System	24 Sep 2020 17:10:31
	System	24 Sep 2020 17:10:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 3'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:17', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e8bd6dc4-9f02-4b52-9b80-65f571e9430a'	System	25 Sep 2020 19:21:31
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 19:21:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:21', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e8bd6dc4-9f02-4b52-9b80-65f571e9430a' User entered 'No (N)'	System	25 Sep 2020 19:21:31
	System	25 Sep 2020 19:21:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:24', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e8bd6dc4-9f02-4b52-9b80-65f571e9430a' User entered 'No (N)'	System	25 Sep 2020 19:21:31
	System	25 Sep 2020 19:21:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:27', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e8bd6dc4-9f02-4b52-9b80-65f571e9430a' User entered 'None (1)'	System	25 Sep 2020 19:21:31
	System	25 Sep 2020 19:21:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:29', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e8bd6dc4-9f02-4b52-9b80-65f571e9430a' User entered '25 Sep 2020 14:21'	System	25 Sep 2020 19:21:31
	System	25 Sep 2020 19:21:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 4'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:32', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ff7785e1-6f2e-4acb-9388-cb08ea382622'	System	27 Sep 2020 02:28:54
User entered 'None (1)'	System	27 Sep 2020 02:28:54

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ff7785e1-6f2e-4acb-9388-cb08ea382622'	System	27 Sep 2020 02:28:54
User entered 'No (N)'	System	27 Sep 2020 02:28:54

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:44', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ff7785e1-6f2e-4acb-9388-cb08ea382622'	System	27 Sep 2020 02:28:54
User entered 'No (N)'	System	27 Sep 2020 02:28:54

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ff7785e1-6f2e-4acb-9388-cb08ea382622'	System	27 Sep 2020 02:28:54
User entered 'None (1)'	System	27 Sep 2020 02:28:54

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:50', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ff7785e1-6f2e-4acb-9388-cb08ea382622'	System	27 Sep 2020 02:28:54
User entered '26 Sep 2020 21:28'	System	27 Sep 2020 02:28:54

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 5'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:48:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'cb0feacb-7cde-4828-ad7c-61e5fe9f93cf'	System	27 Sep 2020 19:48:59
User entered 'None (1)'	System	27 Sep 2020 19:48:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:48:50', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'cb0feacb-7cde-4828-ad7c-61e5fe9f93cf'	System	27 Sep 2020 19:48:59
User entered 'No (N)'	System	27 Sep 2020 19:48:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:48:52', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'cb0feacb-7cde-4828-ad7c-61e5fe9f93cf'	System	27 Sep 2020 19:48:59
User entered 'No (N)'	System	27 Sep 2020 19:48:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:48:55', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'cb0feacb-7cde-4828-ad7c-61e5fe9f93cf' User entered 'None (1)'	System	27 Sep 2020 19:48:59
	System	27 Sep 2020 19:48:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:48:57', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'cb0feacb-7cde-4828-ad7c-61e5fe9f93cf' User entered '27 Sep 2020 14:48'	System	27 Sep 2020 19:48:59
	System	27 Sep 2020 19:48:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 6'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:19', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b6e90b29-a505-4a24-a97d-ce59c45864f5'	System	28 Sep 2020 17:44:38
User entered 'None (1)'	System	28 Sep 2020 17:44:38

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:23', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b6e90b29-a505-4a24-a97d-ce59c45864f5' User entered 'No (N)'	System	28 Sep 2020 17:44:38
	System	28 Sep 2020 17:44:38

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:25', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b6e90b29-a505-4a24-a97d-ce59c45864f5' User entered 'No (N)'	System	28 Sep 2020 17:44:38
	System	28 Sep 2020 17:44:38

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:29', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b6e90b29-a505-4a24-a97d-ce59c45864f5'	System	28 Sep 2020 17:44:38
User entered 'None (1)'	System	28 Sep 2020 17:44:38

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:31', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b6e90b29-a505-4a24-a97d-ce59c45864f5' User entered '28 Sep 2020 12:44'	System	28 Sep 2020 17:44:38
	System	28 Sep 2020 17:44:38

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 7'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:08', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5e97dac3-6826-4811-8754-ea7e2a964b22'	System	29 Sep 2020 17:15:23
User entered 'None (1)'	System	29 Sep 2020 17:15:23

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:11', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5e97dac3-6826-4811-8754-ea7e2a964b22'	System	29 Sep 2020 17:15:23
User entered 'No (N)'	System	29 Sep 2020 17:15:23

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:14', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5e97dac3-6826-4811-8754-ea7e2a964b22'	System	29 Sep 2020 17:15:23
User entered 'No (N)'	System	29 Sep 2020 17:15:23

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:17', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5e97dac3-6826-4811-8754-ea7e2a964b22'	System	29 Sep 2020 17:15:23
User entered 'None (1)'	System	29 Sep 2020 17:15:23

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:19', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5e97dac3-6826-4811-8754-ea7e2a964b22' User entered '29 Sep 2020 12:15'	System	29 Sep 2020 17:15:23
	System	29 Sep 2020 17:15:23

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:25:54', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2260a4fb-8d95-4986-8dfc-1b3c74f3cd7a' User entered 'None (0)'	System	23 Sep 2020 16:26:52
	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:26:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2260a4fb-8d95-4986-8dfc-1b3c74f3cd7a' User entered 'None (0)'	System	23 Sep 2020 16:26:52
	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:26:10', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2260a4fb-8d95-4986-8dfc-1b3c74f3cd7a' User entered 'None (0)'	System	23 Sep 2020 16:26:52
	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:26:16', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2260a4fb-8d95-4986-8dfc-1b3c74f3cd7a' User entered 'None (0)'	System	23 Sep 2020 16:26:52
	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:26:21', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2260a4fb-8d95-4986-8dfc-1b3c74f3cd7a' User entered 'None (0)'	System	23 Sep 2020 16:26:52
	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:26:26', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2260a4fb-8d95-4986-8dfc-1b3c74f3cd7a' User entered 'None (0)'	System	23 Sep 2020 16:26:52
	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:26:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2260a4fb-8d95-4986-8dfc-1b3c74f3cd7a' User entered 'No (N)'	System	23 Sep 2020 16:26:52
	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T11:26:50', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2260a4fb-8d95-4986-8dfc-1b3c74f3cd7a' User entered '23 Sep 2020 11:26'	System	23 Sep 2020 16:26:52
	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Sep 2020 11:23'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Sep 2020 13:53'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:34', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9c88ecf2-9fac-4aef-9007-45d5b5b063ff' User entered 'None (0)'	System	23 Sep 2020 22:52:07
	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:44', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9c88ecf2-9fac-4aef-9007-45d5b5b063ff'	System	23 Sep 2020 22:52:07
User entered 'No interference with activity (1)'	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:51', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9c88ecf2-9fac-4aef-9007-45d5b5b063ff' User entered 'None (0)'	System	23 Sep 2020 22:52:07
	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:53', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9c88ecf2-9fac-4aef-9007-45d5b5b063ff' User entered 'None (0)'	System	23 Sep 2020 22:52:07
	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:56', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9c88ecf2-9fac-4aef-9007-45d5b5b063ff' User entered 'None (0)'	System	23 Sep 2020 22:52:07
	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:51:57', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9c88ecf2-9fac-4aef-9007-45d5b5b063ff' User entered 'None (0)'	System	23 Sep 2020 22:52:07
	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:52:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9c88ecf2-9fac-4aef-9007-45d5b5b063ff' User entered 'No (N)'	System	23 Sep 2020 22:52:07
	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-23T17:52:03', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9c88ecf2-9fac-4aef-9007-45d5b5b063ff' User entered '23 Sep 2020 17:52'	System	23 Sep 2020 22:52:07
	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Sep 2020 14:48'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 2'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:10:34', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e88b859b-3546-49db-9c02-43760ad69823' User entered 'None (0)'	System	24 Sep 2020 17:11:13
	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:10:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e88b859b-3546-49db-9c02-43760ad69823'	System	24 Sep 2020 17:11:13
User entered 'No interference with activity (1)'	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:10:48', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e88b859b-3546-49db-9c02-43760ad69823'	System	24 Sep 2020 17:11:13
User entered 'No interference with activity (1)'	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:10:54', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e88b859b-3546-49db-9c02-43760ad69823' User entered 'None (0)'	System	24 Sep 2020 17:11:13
	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:10:57', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e88b859b-3546-49db-9c02-43760ad69823' User entered 'None (0)'	System	24 Sep 2020 17:11:13
	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:11:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e88b859b-3546-49db-9c02-43760ad69823' User entered 'None (0)'	System	24 Sep 2020 17:11:13
	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:11:08', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e88b859b-3546-49db-9c02-43760ad69823' User entered 'No (N)'	System	24 Sep 2020 17:11:13
	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-24T12:11:10', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e88b859b-3546-49db-9c02-43760ad69823' User entered '24 Sep 2020 12:11'	System	24 Sep 2020 17:11:13
	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 3'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:34', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2d7e12de-f2ae-416d-8ee3-77e4c0b241d9' User entered 'None (0)'	System	25 Sep 2020 19:22:07
	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:36', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2d7e12de-f2ae-416d-8ee3-77e4c0b241d9' User entered 'None (0)'	System	25 Sep 2020 19:22:07
	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2d7e12de-f2ae-416d-8ee3-77e4c0b241d9' User entered 'None (0)'	System	25 Sep 2020 19:22:07
	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:49', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2d7e12de-f2ae-416d-8ee3-77e4c0b241d9' User entered 'None (0)'	System	25 Sep 2020 19:22:07
	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:52', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2d7e12de-f2ae-416d-8ee3-77e4c0b241d9' User entered 'None (0)'	System	25 Sep 2020 19:22:07
	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:54', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2d7e12de-f2ae-416d-8ee3-77e4c0b241d9' User entered 'None (0)'	System	25 Sep 2020 19:22:07
	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:57', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2d7e12de-f2ae-416d-8ee3-77e4c0b241d9' User entered 'No (N)'	System	25 Sep 2020 19:22:07
	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-25T14:21:59', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '2d7e12de-f2ae-416d-8ee3-77e4c0b241d9' User entered '25 Sep 2020 14:21'	System	25 Sep 2020 19:22:07
	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 4'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:53', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9e691fe2-031c-4ed1-a2bf-c1dfcec06dfb' User entered 'None (0)'	System	27 Sep 2020 02:29:12
	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:55', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9e691fe2-031c-4ed1-a2bf-c1dfcec06dfb' User entered 'None (0)'	System	27 Sep 2020 02:29:12
	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:28:58', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9e691fe2-031c-4ed1-a2bf-c1dfcec06dfb' User entered 'None (0)'	System	27 Sep 2020 02:29:12
	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:29:01', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9e691fe2-031c-4ed1-a2bf-c1dfcec06dfb' User entered 'None (0)'	System	27 Sep 2020 02:29:12
	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:29:03', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9e691fe2-031c-4ed1-a2bf-c1dfcec06dfb' User entered 'None (0)'	System	27 Sep 2020 02:29:12
	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:29:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9e691fe2-031c-4ed1-a2bf-c1dfcec06dfb' User entered 'None (0)'	System	27 Sep 2020 02:29:12
	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:29:07', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9e691fe2-031c-4ed1-a2bf-c1dfcec06dfb' User entered 'No (N)'	System	27 Sep 2020 02:29:12
	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-26T21:29:09', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9e691fe2-031c-4ed1-a2bf-c1dfcec06dfb'	System	27 Sep 2020 02:29:12
User entered '26 Sep 2020 21:29'	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 5'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:49:06', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e64a38ea-cea3-46c9-807f-22dc5d24ee0c' User entered 'None (0)'	System	27 Sep 2020 19:49:40
	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:49:08', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e64a38ea-cea3-46c9-807f-22dc5d24ee0c' User entered 'None (0)'	System	27 Sep 2020 19:49:40
	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:49:10', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e64a38ea-cea3-46c9-807f-22dc5d24ee0c' User entered 'None (0)'	System	27 Sep 2020 19:49:40
	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:49:12', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e64a38ea-cea3-46c9-807f-22dc5d24ee0c' User entered 'None (0)'	System	27 Sep 2020 19:49:40
	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:49:15', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e64a38ea-cea3-46c9-807f-22dc5d24ee0c' User entered 'None (0)'	System	27 Sep 2020 19:49:40
	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:49:16', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e64a38ea-cea3-46c9-807f-22dc5d24ee0c' User entered 'None (0)'	System	27 Sep 2020 19:49:40
	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:49:36', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e64a38ea-cea3-46c9-807f-22dc5d24ee0c' User entered 'No (N)'	System	27 Sep 2020 19:49:40
	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-27T14:49:39', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e64a38ea-cea3-46c9-807f-22dc5d24ee0c' User entered '27 Sep 2020 14:49'	System	27 Sep 2020 19:49:40
	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 6'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:35', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '332d5562-fd74-4650-8cc9-fb7795569bb1' User entered 'None (0)'	System	28 Sep 2020 17:44:59
	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:37', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '332d5562-fd74-4650-8cc9-fb7795569bb1' User entered 'None (0)'	System	28 Sep 2020 17:44:59
	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '332d5562-fd74-4650-8cc9-fb7795569bb1' User entered 'None (0)'	System	28 Sep 2020 17:44:59
	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:43', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '332d5562-fd74-4650-8cc9-fb7795569bb1' User entered 'None (0)'	System	28 Sep 2020 17:44:59
	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:45', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '332d5562-fd74-4650-8cc9-fb7795569bb1' User entered 'None (0)'	System	28 Sep 2020 17:44:59
	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '332d5562-fd74-4650-8cc9-fb7795569bb1' User entered 'None (0)'	System	28 Sep 2020 17:44:59
	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:53', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '332d5562-fd74-4650-8cc9-fb7795569bb1' User entered 'No (N)'	System	28 Sep 2020 17:44:59
	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-28T12:44:55', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '332d5562-fd74-4650-8cc9-fb7795569bb1' User entered '28 Sep 2020 12:44'	System	28 Sep 2020 17:44:59
	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	23 Sep 2020 16:12:52
User entered 'Day 7'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:23', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db323e2f-a8ae-4308-aafb-d86363122a5e' User entered 'None (0)'	System	29 Sep 2020 17:15:42
	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:24', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db323e2f-a8ae-4308-aafb-d86363122a5e' User entered 'None (0)'	System	29 Sep 2020 17:15:42
	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:28', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db323e2f-a8ae-4308-aafb-d86363122a5e' User entered 'None (0)'	System	29 Sep 2020 17:15:42
	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:31', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db323e2f-a8ae-4308-aafb-d86363122a5e' User entered 'None (0)'	System	29 Sep 2020 17:15:42
	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:33', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db323e2f-a8ae-4308-aafb-d86363122a5e' User entered 'None (0)'	System	29 Sep 2020 17:15:42
	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:35', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db323e2f-a8ae-4308-aafb-d86363122a5e' User entered 'None (0)'	System	29 Sep 2020 17:15:42
	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:38', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db323e2f-a8ae-4308-aafb-d86363122a5e' User entered 'No (N)'	System	29 Sep 2020 17:15:42
	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-09-29T12:15:40', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db323e2f-a8ae-4308-aafb-d86363122a5e' User entered '29 Sep 2020 12:15'	System	29 Sep 2020 17:15:42
	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 16:12:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 16:12:52

US3492243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	30 Sep 2020 21:40:20

US3492243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '30 Sep 2020'	(b) (4) Addis Mekonnen (b) (4)	30 Sep 2020 21:40:20

US3492243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Contact Made (CONTACT MADE)'	Addis Mekonnen (b) (4)	01 Oct 2020 14:08:39
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Addis Mekonnen (b) (4)	30 Sep 2020 21:40:20
	(b) (4)	

US3492243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty; reason for change Data Entry Error	Addis Mekonnen (b) (4)	01 Oct 2020 14:08:39
User entered 'call attempted @16:41pm'	Addis Mekonnen (b) (4)	30 Sep 2020 21:40:20

US3492243

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	01 Oct 2020 14:09:36

US3492243

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'I'	System	01 Oct 2020 14:09:36

US3492243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:58:22

US3492243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:58:22

US3492243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:58:22

US3492243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:58:22

US3492243

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:58:27

US3492243

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'I'	System	09 Oct 2020 15:58:27

US3492243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	15 Oct 2020 15:45:35

US3492243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '14 Oct 2020'	(b) (4) Gizelle Alvarez (b) (4)	15 Oct 2020 15:45:35

US3492243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Contact Made (CONTACT MADE)'	Gizelle Alvarez (b) (4)	15 Oct 2020 15:45:35

US3492243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Gizelle Alvarez (b) (4)	15 Oct 2020 15:45:35

US3492243

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	15 Oct 2020 15:45:39

US3492243

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'I'	System	15 Oct 2020 15:45:39

US3492243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:30

US3492243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,22NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 04:24:29
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,22NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'no kits available 21OCT2020. sample collected 22NOV2020.' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	03 Dec 2020 21:49:13
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,22NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 07:20:32
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	02 Dec 2020 07:20:23
' canceled (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	02 Dec 2020 07:20:08
' (Site from DM).		
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 14:35:30

US3492243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[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 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:35:30

US3492243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'VISIT2'	System	21 Oct 2020 14:35:30

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 15:44:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Nusirat Williams (b) (4)	21 Oct 2020 15:44:00
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	21 Oct 2020 14:36:22
	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '09:23'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '21 Oct 2020 09:23'	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '36' C	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '68'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'bpm'	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'breaths/min'	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '128'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'mmHg'	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '81'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'mmHg'	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 15:44:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Nusirat Williams (b) (4)	21 Oct 2020 15:44:00
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	21 Oct 2020 14:36:22
	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 15:44:00
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '10:42' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 15:44:00
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '21 Oct 2020 10:42'	System	21 Oct 2020 15:44:00
User entered empty.	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '36.3' C reason for change: Data Entry Error	(b) (4)	21 Oct 2020 15:44:00
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 15:44:00
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'tympanic' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 15:44:00
User entered empty.	Nusirat Williams (b) (4)	21 Oct 2020 14:36:22
	(b) (4), (b) (6)	

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '57' reason for change: Data Entry Error	(b) (4)	
	Nusirat Williams (b) (4)	21 Oct 2020 15:44:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'bpm'	System	21 Oct 2020 15:44:00
User entered empty.	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Nusirat Williams (b) (4)	21 Oct 2020 15:44:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'breaths/min'	System	21 Oct 2020 15:44:00
User entered empty.	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '124' reason for change: Data Entry Error	(b) (4)	
	Nusirat Williams (b) (4)	21 Oct 2020 15:44:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'mmHg'	System	21 Oct 2020 15:44:00
User entered empty.	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '84' reason for change: Data Entry Error	(b) (4)	
	Nusirat Williams (b) (4)	21 Oct 2020 15:44:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'mmHg'	System	21 Oct 2020 15:44:00
User entered empty.	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:35

US3492243

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 14:36:35

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

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 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	Nusirat Williams (b) (4)	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '21 Oct 2020'	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '10:35'	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '21 Oct 2020 10:35'	System	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Right Arm (RIGHT ARM)'	Nusirat Williams (b) (4)	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'ONCE'	System	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:25

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:47

US3492243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:47

US3492243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:47

US3492243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered empty.	System	21 Oct 2020 15:40:47

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nusirat Williams (b) (4)	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:25

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered empty.	System	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nusirat Williams (b) (4)	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered empty.	System	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	21 Oct 2020 15:40:57

US3492243

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '1'	System	21 Oct 2020 15:40:57

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:55:15', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd527c670-cd68-425c-8e58-783c08599809' User entered 'Yes (Y)'	System	21 Oct 2020 15:55:36
	System	21 Oct 2020 15:55:36

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:55:24', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd527c670-cd68-425c-8e58-783c08599809' User entered '97.3'	System	21 Oct 2020 15:55:36
	System	21 Oct 2020 15:55:36

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:55:29', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd527c670-cd68-425c-8e58-783c08599809' User entered 'No (N)'	System	21 Oct 2020 15:55:36
	System	21 Oct 2020 15:55:36

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:55:33', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd527c670-cd68-425c-8e58-783c08599809' User entered '21 Oct 2020 10:55'	System	21 Oct 2020 15:55:36
	System	21 Oct 2020 15:55:36

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '21 Oct 2020 10:55'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '21 Oct 2020 13:25'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:27:52', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4059b9ae-44e5-41a7-90ff-397c85742c28' User entered 'Yes (Y)'	System	22 Oct 2020 09:28:17
	System	22 Oct 2020 09:28:17

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:27:56', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4059b9ae-44e5-41a7-90ff-397c85742c28' User entered '98.6'	System	22 Oct 2020 09:28:17
	System	22 Oct 2020 09:28:17

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:28:09', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4059b9ae-44e5-41a7-90ff-397c85742c28'	System	22 Oct 2020 09:28:17
User entered 'No (N)'	System	22 Oct 2020 09:28:17

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:28:11', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4059b9ae-44e5-41a7-90ff-397c85742c28' User entered '22 Oct 2020 04:28'	System	22 Oct 2020 09:28:17
	System	22 Oct 2020 09:28:17

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '21 Oct 2020 14:20'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 2'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:00:17', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8b198149-2c0f-4c99-86b4-7fe059317264' User entered 'Yes (Y)'	System	22 Oct 2020 17:01:51
	System	22 Oct 2020 17:01:51

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:01:23', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8b198149-2c0f-4c99-86b4-7fe059317264' User entered '99.1'	System	22 Oct 2020 17:01:51
	System	22 Oct 2020 17:01:51

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:01:29', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8b198149-2c0f-4c99-86b4-7fe059317264' User entered 'No (N)'	System	22 Oct 2020 17:01:51
	System	22 Oct 2020 17:01:51

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:01:32', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8b198149-2c0f-4c99-86b4-7fe059317264' User entered '22 Oct 2020 12:01'	System	22 Oct 2020 17:01:51
	System	22 Oct 2020 17:01:51

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 3'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:21:26', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1c288762-a538-4133-b313-964190c773f3' User entered 'Yes (Y)'	System	24 Oct 2020 15:22:46
	System	24 Oct 2020 15:22:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:22:37', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1c288762-a538-4133-b313-964190c773f3' User entered '98.2'	System	24 Oct 2020 15:22:46
	System	24 Oct 2020 15:22:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:22:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1c288762-a538-4133-b313-964190c773f3' User entered 'No (N)'	System	24 Oct 2020 15:22:46
	System	24 Oct 2020 15:22:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:22:44', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1c288762-a538-4133-b313-964190c773f3' User entered '24 Oct 2020 10:22'	System	24 Oct 2020 15:22:46
	System	24 Oct 2020 15:22:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 4'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:00:19', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9088fc86-253e-41fe-b748-c5caac15bf4b' User entered 'Yes (Y)'	System	24 Oct 2020 17:00:54
	System	24 Oct 2020 17:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:00:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9088fc86-253e-41fe-b748-c5caac15bf4b' User entered '98.3'	System	24 Oct 2020 17:00:54
	System	24 Oct 2020 17:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:00:50', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9088fc86-253e-41fe-b748-c5caac15bf4b' User entered 'No (N)'	System	24 Oct 2020 17:00:54
	System	24 Oct 2020 17:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:00:52', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9088fc86-253e-41fe-b748-c5caac15bf4b' User entered '24 Oct 2020 12:00'	System	24 Oct 2020 17:00:54
	System	24 Oct 2020 17:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 5'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:30:30', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '84dd7b38-5c49-44d0-800f-0ad962b96e68' User entered 'Yes (Y)'	System	26 Oct 2020 16:30:46
	System	26 Oct 2020 16:30:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:30:36', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '84dd7b38-5c49-44d0-800f-0ad962b96e68' User entered '98.3'	System	26 Oct 2020 16:30:46
	System	26 Oct 2020 16:30:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:30:40', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '84dd7b38-5c49-44d0-800f-0ad962b96e68'	System	26 Oct 2020 16:30:46
User entered 'No (N)'	System	26 Oct 2020 16:30:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:30:43', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '84dd7b38-5c49-44d0-800f-0ad962b96e68' User entered '26 Oct 2020 11:30'	System	26 Oct 2020 16:30:46
	System	26 Oct 2020 16:30:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 6'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:02', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5fc482fd-2a0f-4b6f-8847-c8e393470a76'	System	27 Oct 2020 15:45:39
User entered 'Yes (Y)'	System	27 Oct 2020 15:45:39

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:26', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5fc482fd-2a0f-4b6f-8847-c8e393470a76' User entered '98.5'	System	27 Oct 2020 15:45:39
	System	27 Oct 2020 15:45:39

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:30', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5fc482fd-2a0f-4b6f-8847-c8e393470a76'	System	27 Oct 2020 15:45:39
User entered 'No (N)'	System	27 Oct 2020 15:45:39

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:33', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5fc482fd-2a0f-4b6f-8847-c8e393470a76' User entered '27 Oct 2020 10:45'	System	27 Oct 2020 15:45:39
	System	27 Oct 2020 15:45:39

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 7'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:15:02', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'cf9ae838-63e9-45ae-a51e-1c02962da8a0' User entered 'Yes (Y)'	System	28 Oct 2020 12:15:52
	System	28 Oct 2020 12:15:52

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:15:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'cf9ae838-63e9-45ae-a51e-1c02962da8a0' User entered '98.5'	System	28 Oct 2020 12:15:52
	System	28 Oct 2020 12:15:52

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:15:45', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'cf9ae838-63e9-45ae-a51e-1c02962da8a0' User entered 'No (N)'	System	28 Oct 2020 12:15:52
	System	28 Oct 2020 12:15:52

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:15:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'cf9ae838-63e9-45ae-a51e-1c02962da8a0' User entered '28 Oct 2020 07:15'	System	28 Oct 2020 12:15:52
	System	28 Oct 2020 12:15:52

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:55:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '39591f76-7655-4710-aa36-c406550575bd' User entered 'None (1)'	System	21 Oct 2020 15:55:56
	System	21 Oct 2020 15:55:56

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:55:44', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '39591f76-7655-4710-aa36-c406550575bd' User entered 'No (N)'	System	21 Oct 2020 15:55:56
	System	21 Oct 2020 15:55:56

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:55:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '39591f76-7655-4710-aa36-c406550575bd' User entered 'No (N)'	System	21 Oct 2020 15:55:56
	System	21 Oct 2020 15:55:56

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:55:50', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '39591f76-7655-4710-aa36-c406550575bd' User entered 'None (1)'	System	21 Oct 2020 15:55:56
	System	21 Oct 2020 15:55:56

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:55:52', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '39591f76-7655-4710-aa36-c406550575bd' User entered '21 Oct 2020 10:55'	System	21 Oct 2020 15:55:56
	System	21 Oct 2020 15:55:56

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '21 Oct 2020 10:55'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '21 Oct 2020 13:25'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:28:32', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '279217ee-6001-4f63-b267-63f40dd263a9'	System	22 Oct 2020 09:28:51
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Oct 2020 09:28:51

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:28:38', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '279217ee-6001-4f63-b267-63f40dd263a9' User entered 'No (N)'	System	22 Oct 2020 09:28:51
	System	22 Oct 2020 09:28:51

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:28:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '279217ee-6001-4f63-b267-63f40dd263a9' User entered 'No (N)'	System	22 Oct 2020 09:28:51
	System	22 Oct 2020 09:28:51

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:28:45', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '279217ee-6001-4f63-b267-63f40dd263a9' User entered 'None (1)'	System	22 Oct 2020 09:28:51
	System	22 Oct 2020 09:28:51

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:28:48', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '279217ee-6001-4f63-b267-63f40dd263a9' User entered '22 Oct 2020 04:28'	System	22 Oct 2020 09:28:51
	System	22 Oct 2020 09:28:51

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '21 Oct 2020 14:20'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 2'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:01:44', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b9bde65e-16da-4c20-a09f-1254f4c1f64f'	System	22 Oct 2020 17:02:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Oct 2020 17:02:09

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:01:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b9bde65e-16da-4c20-a09f-1254f4c1f64f' User entered 'No (N)'	System	22 Oct 2020 17:02:09
	System	22 Oct 2020 17:02:09

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:01:49', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b9bde65e-16da-4c20-a09f-1254f4c1f64f' User entered 'No (N)'	System	22 Oct 2020 17:02:09
	System	22 Oct 2020 17:02:09

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:01:53', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b9bde65e-16da-4c20-a09f-1254f4c1f64f' User entered 'None (1)'	System	22 Oct 2020 17:02:09
	System	22 Oct 2020 17:02:09

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:01:56', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b9bde65e-16da-4c20-a09f-1254f4c1f64f' User entered '22 Oct 2020 12:01'	System	22 Oct 2020 17:02:09
	System	22 Oct 2020 17:02:09

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 3'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:21:02', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8befd9ac-3cf4-4361-84a6-02400b6b5523' User entered 'None (1)'	System	24 Oct 2020 15:21:19
	System	24 Oct 2020 15:21:19

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:21:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8befd9ac-3cf4-4361-84a6-02400b6b5523'	System	24 Oct 2020 15:21:19
User entered 'No (N)'	System	24 Oct 2020 15:21:19

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:21:09', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8befd9ac-3cf4-4361-84a6-02400b6b5523'	System	24 Oct 2020 15:21:19
User entered 'No (N)'	System	24 Oct 2020 15:21:19

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:21:14', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8befd9ac-3cf4-4361-84a6-02400b6b5523' User entered 'None (1)'	System	24 Oct 2020 15:21:19
	System	24 Oct 2020 15:21:19

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:21:17', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8befd9ac-3cf4-4361-84a6-02400b6b5523' User entered '24 Oct 2020 10:21'	System	24 Oct 2020 15:21:19
	System	24 Oct 2020 15:21:19

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 4'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:00:57', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f55b0137-6bda-4ddb-853b-4a220fe6d4f8'	System	24 Oct 2020 17:01:11
User entered 'None (1)'	System	24 Oct 2020 17:01:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:00:59', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f55b0137-6bda-4ddb-853b-4a220fe6d4f8'	System	24 Oct 2020 17:01:11
User entered 'No (N)'	System	24 Oct 2020 17:01:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:03', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f55b0137-6bda-4ddb-853b-4a220fe6d4f8'	System	24 Oct 2020 17:01:11
User entered 'No (N)'	System	24 Oct 2020 17:01:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:05', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f55b0137-6bda-4ddb-853b-4a220fe6d4f8' User entered 'None (1)'	System	24 Oct 2020 17:01:11
	System	24 Oct 2020 17:01:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:08', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f55b0137-6bda-4ddb-853b-4a220fe6d4f8' User entered '24 Oct 2020 12:01'	System	24 Oct 2020 17:01:11
	System	24 Oct 2020 17:01:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 5'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:30:47', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '834a2e6e-ab29-48af-a930-02549b0dca25'	System	26 Oct 2020 16:31:00
User entered 'None (1)'	System	26 Oct 2020 16:31:00

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:30:50', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '834a2e6e-ab29-48af-a930-02549b0dca25' User entered 'No (N)'	System	26 Oct 2020 16:31:00
	System	26 Oct 2020 16:31:00

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:30:52', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '834a2e6e-ab29-48af-a930-02549b0dca25' User entered 'No (N)'	System	26 Oct 2020 16:31:00
	System	26 Oct 2020 16:31:00

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:30:55', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '834a2e6e-ab29-48af-a930-02549b0dca25' User entered 'None (1)'	System	26 Oct 2020 16:31:00
	System	26 Oct 2020 16:31:00

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:30:58', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '834a2e6e-ab29-48af-a930-02549b0dca25' User entered '26 Oct 2020 11:30'	System	26 Oct 2020 16:31:00
	System	26 Oct 2020 16:31:00

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 6'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:36', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5cb735d0-8239-4f05-a245-285e8b268afe' User entered 'None (1)'	System	27 Oct 2020 15:45:49
	System	27 Oct 2020 15:45:49

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:39', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5cb735d0-8239-4f05-a245-285e8b268afe' User entered 'No (N)'	System	27 Oct 2020 15:45:49
	System	27 Oct 2020 15:45:49

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5cb735d0-8239-4f05-a245-285e8b268afe' User entered 'No (N)'	System	27 Oct 2020 15:45:49
	System	27 Oct 2020 15:45:49

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:43', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5cb735d0-8239-4f05-a245-285e8b268afe' User entered 'None (1)'	System	27 Oct 2020 15:45:49
	System	27 Oct 2020 15:45:49

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:46', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '5cb735d0-8239-4f05-a245-285e8b268afe' User entered '27 Oct 2020 10:45'	System	27 Oct 2020 15:45:49
	System	27 Oct 2020 15:45:49

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 7'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:15:51', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3a221b23-2f92-4782-a858-c4f95125c560'	System	28 Oct 2020 12:16:11
User entered 'None (1)'	System	28 Oct 2020 12:16:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:15:56', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3a221b23-2f92-4782-a858-c4f95125c560'	System	28 Oct 2020 12:16:11
User entered 'No (N)'	System	28 Oct 2020 12:16:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:01', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3a221b23-2f92-4782-a858-c4f95125c560'	System	28 Oct 2020 12:16:11
User entered 'No (N)'	System	28 Oct 2020 12:16:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3a221b23-2f92-4782-a858-c4f95125c560'	System	28 Oct 2020 12:16:11
User entered 'None (1)'	System	28 Oct 2020 12:16:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:07', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3a221b23-2f92-4782-a858-c4f95125c560' User entered '28 Oct 2020 07:16'	System	28 Oct 2020 12:16:11
	System	28 Oct 2020 12:16:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:55:57', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8497ce7c-9684-47ba-b5e7-91ef33ac2de3' User entered 'None (0)'	System	21 Oct 2020 15:56:22
	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:56:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8497ce7c-9684-47ba-b5e7-91ef33ac2de3' User entered 'None (0)'	System	21 Oct 2020 15:56:22
	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:56:03', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8497ce7c-9684-47ba-b5e7-91ef33ac2de3' User entered 'None (0)'	System	21 Oct 2020 15:56:22
	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:56:06', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8497ce7c-9684-47ba-b5e7-91ef33ac2de3' User entered 'None (0)'	System	21 Oct 2020 15:56:22
	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:56:08', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8497ce7c-9684-47ba-b5e7-91ef33ac2de3' User entered 'None (0)'	System	21 Oct 2020 15:56:22
	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:56:10', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8497ce7c-9684-47ba-b5e7-91ef33ac2de3' User entered 'None (0)'	System	21 Oct 2020 15:56:22
	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:56:14', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8497ce7c-9684-47ba-b5e7-91ef33ac2de3' User entered 'No (N)'	System	21 Oct 2020 15:56:22
	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-21T10:56:17', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '8497ce7c-9684-47ba-b5e7-91ef33ac2de3' User entered '21 Oct 2020 10:56'	System	21 Oct 2020 15:56:22
	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '21 Oct 2020 10:55'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '21 Oct 2020 13:25'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:28:56', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9050a8e2-0f37-4722-841e-049f79c53757'	System	22 Oct 2020 09:29:28
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:29:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9050a8e2-0f37-4722-841e-049f79c53757'	System	22 Oct 2020 09:29:28
User entered 'Some interference with activity (2)'	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:29:08', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9050a8e2-0f37-4722-841e-049f79c53757'	System	22 Oct 2020 09:29:28
User entered 'Some interference with activity (2)'	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:29:12', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9050a8e2-0f37-4722-841e-049f79c53757'	System	22 Oct 2020 09:29:28
User entered 'Some interference with activity (2)'	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:29:15', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9050a8e2-0f37-4722-841e-049f79c53757' User entered 'None (0)'	System	22 Oct 2020 09:29:28
	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:29:18', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9050a8e2-0f37-4722-841e-049f79c53757' User entered 'None (0)'	System	22 Oct 2020 09:29:28
	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:29:23', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9050a8e2-0f37-4722-841e-049f79c53757' User entered 'No (N)'	System	22 Oct 2020 09:29:28
	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T04:29:26', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '9050a8e2-0f37-4722-841e-049f79c53757' User entered '22 Oct 2020 04:29'	System	22 Oct 2020 09:29:28
	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '21 Oct 2020 14:20'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 2'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:02:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c538fdf3-33d0-459d-877c-ca6e55e4bd29' User entered 'None (0)'	System	22 Oct 2020 17:02:56
	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:02:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c538fdf3-33d0-459d-877c-ca6e55e4bd29'	System	22 Oct 2020 17:02:56
User entered 'Some interference with activity (2)'	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:02:07', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c538fdf3-33d0-459d-877c-ca6e55e4bd29'	System	22 Oct 2020 17:02:56
User entered 'Some interference with activity (2)'	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:02:10', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c538fdf3-33d0-459d-877c-ca6e55e4bd29'	System	22 Oct 2020 17:02:56
User entered 'Some interference with activity (2)'	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:02:12', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c538fdf3-33d0-459d-877c-ca6e55e4bd29' User entered 'None (0)'	System	22 Oct 2020 17:02:56
	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:02:23', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c538fdf3-33d0-459d-877c-ca6e55e4bd29'	System	22 Oct 2020 17:02:56
User entered 'Some interference with activity not requiring medical attention (2)'	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:02:26', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c538fdf3-33d0-459d-877c-ca6e55e4bd29' User entered 'No (N)'	System	22 Oct 2020 17:02:56
	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-22T12:02:28', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c538fdf3-33d0-459d-877c-ca6e55e4bd29' User entered '22 Oct 2020 12:02'	System	22 Oct 2020 17:02:56
	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 3'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:22:48', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '08ae1bd2-f609-4dd3-a0b8-9c71572976d6' User entered 'None (0)'	System	24 Oct 2020 15:23:13
	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:22:54', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '08ae1bd2-f609-4dd3-a0b8-9c71572976d6'	System	24 Oct 2020 15:23:13
User entered 'No interference with activity (1)'	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:22:58', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '08ae1bd2-f609-4dd3-a0b8-9c71572976d6'	System	24 Oct 2020 15:23:13
User entered 'No interference with activity (1)'	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:23:02', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '08ae1bd2-f609-4dd3-a0b8-9c71572976d6' User entered 'No interference with activity (1)'	System	24 Oct 2020 15:23:13
	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:23:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '08ae1bd2-f609-4dd3-a0b8-9c71572976d6' User entered 'None (0)'	System	24 Oct 2020 15:23:13
	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:23:06', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '08ae1bd2-f609-4dd3-a0b8-9c71572976d6' User entered 'None (0)'	System	24 Oct 2020 15:23:13
	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:23:09', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '08ae1bd2-f609-4dd3-a0b8-9c71572976d6' User entered 'No (N)'	System	24 Oct 2020 15:23:13
	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T10:23:11', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '08ae1bd2-f609-4dd3-a0b8-9c71572976d6' User entered '24 Oct 2020 10:23'	System	24 Oct 2020 15:23:13
	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 4'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:11', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '30dadf5f-532d-443b-b63e-78e41ae9651a' User entered 'None (0)'	System	24 Oct 2020 17:01:35
	System	24 Oct 2020 17:01:35

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:14', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '30dadf5f-532d-443b-b63e-78e41ae9651a'	System	24 Oct 2020 17:01:35
User entered 'No interference with activity (1)'	System	24 Oct 2020 17:01:35

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:16', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '30dadf5f-532d-443b-b63e-78e41ae9651a'	System	24 Oct 2020 17:01:35
User entered 'No interference with activity (1)'	System	24 Oct 2020 17:01:35

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:19', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '30dadf5f-532d-443b-b63e-78e41ae9651a'	System	24 Oct 2020 17:01:35
User entered 'No interference with activity (1)'	System	24 Oct 2020 17:01:35

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:20', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '30dadf5f-532d-443b-b63e-78e41ae9651a' User entered 'None (0)'	System	24 Oct 2020 17:01:35
	System	24 Oct 2020 17:01:35

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:22', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '30dadf5f-532d-443b-b63e-78e41ae9651a' User entered 'None (0)'	System	24 Oct 2020 17:01:35
	System	24 Oct 2020 17:01:35

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:26', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '30dadf5f-532d-443b-b63e-78e41ae9651a' User entered 'No (N)'	System	24 Oct 2020 17:01:35
	System	24 Oct 2020 17:01:35

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-24T12:01:29', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '30dadf5f-532d-443b-b63e-78e41ae9651a' User entered '24 Oct 2020 12:01'	System	24 Oct 2020 17:01:35
	System	24 Oct 2020 17:01:35

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 5'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:31:02', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1573c8bc-e2ea-4eb6-b0df-3d7abeefb538' User entered 'None (0)'	System	26 Oct 2020 16:31:19
	System	26 Oct 2020 16:31:19

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:31:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1573c8bc-e2ea-4eb6-b0df-3d7abeefb538' User entered 'None (0)'	System	26 Oct 2020 16:31:19
	System	26 Oct 2020 16:31:19

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:31:05', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1573c8bc-e2ea-4eb6-b0df-3d7abeefb538'	System	26 Oct 2020 16:31:19
User entered 'None (0)'	System	26 Oct 2020 16:31:19

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:31:07', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1573c8bc-e2ea-4eb6-b0df-3d7abeefb538' User entered 'None (0)'	System	26 Oct 2020 16:31:19
	System	26 Oct 2020 16:31:19

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:31:09', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1573c8bc-e2ea-4eb6-b0df-3d7abeefb538' User entered 'None (0)'	System	26 Oct 2020 16:31:19
	System	26 Oct 2020 16:31:19

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:31:11', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1573c8bc-e2ea-4eb6-b0df-3d7abeefb538' User entered 'None (0)'	System	26 Oct 2020 16:31:19
	System	26 Oct 2020 16:31:19

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:31:14', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1573c8bc-e2ea-4eb6-b0df-3d7abeefb538'	System	26 Oct 2020 16:31:19
User entered 'No (N)'	System	26 Oct 2020 16:31:19

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-26T11:31:16', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '1573c8bc-e2ea-4eb6-b0df-3d7abeefb538' User entered '26 Oct 2020 11:31'	System	26 Oct 2020 16:31:19
	System	26 Oct 2020 16:31:19

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 6'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:49', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a39f13a5-1400-41f9-8aff-bd7e532a88dc' User entered 'None (0)'	System	27 Oct 2020 15:46:07
	System	27 Oct 2020 15:46:07

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:51', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a39f13a5-1400-41f9-8aff-bd7e532a88dc' User entered 'None (0)'	System	27 Oct 2020 15:46:07
	System	27 Oct 2020 15:46:07

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:53', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a39f13a5-1400-41f9-8aff-bd7e532a88dc' User entered 'None (0)'	System	27 Oct 2020 15:46:07
	System	27 Oct 2020 15:46:07

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:55', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a39f13a5-1400-41f9-8aff-bd7e532a88dc' User entered 'None (0)'	System	27 Oct 2020 15:46:07
	System	27 Oct 2020 15:46:07

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:57', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a39f13a5-1400-41f9-8aff-bd7e532a88dc' User entered 'None (0)'	System	27 Oct 2020 15:46:07
	System	27 Oct 2020 15:46:07

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:45:59', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a39f13a5-1400-41f9-8aff-bd7e532a88dc' User entered 'None (0)'	System	27 Oct 2020 15:46:07
	System	27 Oct 2020 15:46:07

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:46:02', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a39f13a5-1400-41f9-8aff-bd7e532a88dc' User entered 'No (N)'	System	27 Oct 2020 15:46:07
	System	27 Oct 2020 15:46:07

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-27T10:46:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a39f13a5-1400-41f9-8aff-bd7e532a88dc' User entered '27 Oct 2020 10:46'	System	27 Oct 2020 15:46:07
	System	27 Oct 2020 15:46:07

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	21 Oct 2020 15:40:40
User entered 'Day 7'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:12', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '6b1bd05c-d6d9-41f8-9cd2-63d9ef7b3087' User entered 'None (0)'	System	28 Oct 2020 12:16:41
	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:16', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '6b1bd05c-d6d9-41f8-9cd2-63d9ef7b3087'	System	28 Oct 2020 12:16:41
User entered 'No interference with activity (1)'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:21', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '6b1bd05c-d6d9-41f8-9cd2-63d9ef7b3087' User entered 'None (0)'	System	28 Oct 2020 12:16:41
	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:27', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '6b1bd05c-d6d9-41f8-9cd2-63d9ef7b3087' User entered 'None (0)'	System	28 Oct 2020 12:16:41
	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:29', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '6b1bd05c-d6d9-41f8-9cd2-63d9ef7b3087' User entered 'None (0)'	System	28 Oct 2020 12:16:41
	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:33', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '6b1bd05c-d6d9-41f8-9cd2-63d9ef7b3087' User entered 'None (0)'	System	28 Oct 2020 12:16:41
	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:36', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '6b1bd05c-d6d9-41f8-9cd2-63d9ef7b3087' User entered 'No (N)'	System	28 Oct 2020 12:16:41
	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T07:16:39', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '6b1bd05c-d6d9-41f8-9cd2-63d9ef7b3087' User entered '28 Oct 2020 07:16'	System	28 Oct 2020 12:16:41
	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 15:40:40

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	28 Oct 2020 12:16:41
User entered 'Day 8'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T14:32:15', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3842767e-54bf-4c14-9b23-c398ad6d45a9'	System	28 Oct 2020 19:32:19
User entered 'No interference with activity (1)'	System	28 Oct 2020 19:32:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T14:32:18', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '3842767e-54bf-4c14-9b23-c398ad6d45a9' User entered '28 Oct 2020 14:32'	System	28 Oct 2020 19:32:19
	System	28 Oct 2020 19:32:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Oct 2020 12:00'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	28 Oct 2020 12:16:41
User entered 'Day 9'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-30T09:35:48', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '6430caa4-450c-4833-be74-0c6314b5b07a' User entered 'Some interference with activity (2)'	System	30 Oct 2020 14:35:56
	System	30 Oct 2020 14:35:56

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-30T09:35:51', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '6430caa4-450c-4833-be74-0c6314b5b07a' User entered '30 Oct 2020 09:35'	System	30 Oct 2020 14:35:56
	System	30 Oct 2020 14:35:56

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	28 Oct 2020 19:32:19
User entered 'Day 10'	System	28 Oct 2020 19:32:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-30T13:55:55', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b67ffa6a-e6d6-4810-b841-2a7a1eab4d22'	System	30 Oct 2020 18:56:00
User entered 'Some interference with activity (2)'	System	30 Oct 2020 18:56:00

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-30T13:55:57', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'b67ffa6a-e6d6-4810-b841-2a7a1eab4d22'	System	30 Oct 2020 18:56:00
User entered '30 Oct 2020 13:55'	System	30 Oct 2020 18:56:00

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 19:32:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 19:32:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	30 Oct 2020 14:35:56
User entered 'Day 11'	System	30 Oct 2020 14:35:56

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:01:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-31T12:06:58', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a2b2682b-39fb-4614-85ee-fa1cde1a623f' User entered 'No interference with activity (1)'	System	31 Oct 2020 17:07:04
	System	31 Oct 2020 17:07:04

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-31T12:07:01', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a2b2682b-39fb-4614-85ee-fa1cde1a623f' User entered '31 Oct 2020 12:07'	System	31 Oct 2020 17:07:04
	System	31 Oct 2020 17:07:04

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:35:56

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:35:56

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	30 Oct 2020 18:56:00
User entered 'Day 12'	System	30 Oct 2020 18:56:00

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:01:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-01T23:59:13', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'af4590a0-27f5-44c7-ac81-1ac4b5dd2f53'	System	02 Nov 2020 05:59:19
User entered 'No interference with activity (1)'	System	02 Nov 2020 05:59:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-01T23:59:16', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'af4590a0-27f5-44c7-ac81-1ac4b5dd2f53' User entered '01 Nov 2020 23:59'	System	02 Nov 2020 05:59:19
	System	02 Nov 2020 05:59:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 18:56:00

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 18:56:00

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	31 Oct 2020 17:07:04
User entered 'Day 13'	System	31 Oct 2020 17:07:04

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:01:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-02T12:50:31', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '67671a0c-9549-4106-8dd2-7e55b77bfa1d'	System	02 Nov 2020 18:50:39
User entered 'Some interference with activity (2)'	System	02 Nov 2020 18:50:39

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-02T12:50:34', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '67671a0c-9549-4106-8dd2-7e55b77bfa1d' User entered '02 Nov 2020 12:50'	System	02 Nov 2020 18:50:39
	System	02 Nov 2020 18:50:39

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 17:07:04

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 17:07:04

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	02 Nov 2020 05:59:19
User entered 'Day 14'	System	02 Nov 2020 05:59:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:01:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-03T12:00:49', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ab2da7db-d33d-4f7a-ae35-99e2b76b0346'	System	03 Nov 2020 18:00:54
User entered 'Some interference with activity (2)'	System	03 Nov 2020 18:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-03T12:00:52', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ab2da7db-d33d-4f7a-ae35-99e2b76b0346' User entered '03 Nov 2020 12:00'	System	03 Nov 2020 18:00:54
	System	03 Nov 2020 18:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 05:59:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 05:59:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	02 Nov 2020 18:50:39
User entered 'Day 15'	System	02 Nov 2020 18:50:39

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:01:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-04T12:00:15', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '98b50203-c358-4bae-a46f-a67ee85435fc'	System	04 Nov 2020 18:00:27
User entered 'No interference with activity (1)'	System	04 Nov 2020 18:00:27

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-04T12:00:17', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '98b50203-c358-4bae-a46f-a67ee85435fc'	System	04 Nov 2020 18:00:27
User entered '04 Nov 2020 12:00'	System	04 Nov 2020 18:00:27

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 18:50:39

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 18:50:39

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	03 Nov 2020 18:00:54
User entered 'Day 16'	System	03 Nov 2020 18:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:01:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 18:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 18:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	04 Nov 2020 18:00:27
User entered 'Day 17'	System	04 Nov 2020 18:00:27

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:01:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-06T15:30:21', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '67d4c9ae-1cfc-477b-861e-05eb0472fbf4' User entered 'None (0)'	System	06 Nov 2020 21:30:29
	System	06 Nov 2020 21:30:29

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-06T15:30:24', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '67d4c9ae-1cfc-477b-861e-05eb0472fbf4' User entered '06 Nov 2020 15:30'	System	06 Nov 2020 21:30:29
	System	06 Nov 2020 21:30:29

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 18:00:27

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 18:00:27

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	28 Oct 2020 12:16:41
User entered 'Day 8'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T14:32:22', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '88a18c4e-66b0-40af-b9b7-bbdda184eea3' User entered 'No (N)'	System	28 Oct 2020 19:32:29
	System	28 Oct 2020 19:32:29

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-28T14:32:25', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '88a18c4e-66b0-40af-b9b7-bbdda184eea3' User entered '28 Oct 2020 14:32'	System	28 Oct 2020 19:32:29
	System	28 Oct 2020 19:32:29

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '28 Oct 2020 12:00'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	28 Oct 2020 12:16:41
User entered 'Day 9'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-30T09:35:55', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '74a3fb53-b96f-4ef3-b32d-43672f382df5' User entered 'No (N)'	System	30 Oct 2020 14:36:02
	System	30 Oct 2020 14:36:02

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-30T09:35:58', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '74a3fb53-b96f-4ef3-b32d-43672f382df5' User entered '30 Oct 2020 09:35'	System	30 Oct 2020 14:36:02
	System	30 Oct 2020 14:36:02

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	28 Oct 2020 19:32:19
User entered 'Day 10'	System	28 Oct 2020 19:32:19

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-30T13:56:03', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a99894f1-495e-4681-b8a2-f96c3984c02c' User entered 'No (N)'	System	30 Oct 2020 18:56:09
	System	30 Oct 2020 18:56:09

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-30T13:56:06', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a99894f1-495e-4681-b8a2-f96c3984c02c' User entered '30 Oct 2020 13:56'	System	30 Oct 2020 18:56:09
	System	30 Oct 2020 18:56:09

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 19:32:19

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 19:32:19

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	30 Oct 2020 14:35:56
User entered 'Day 11'	System	30 Oct 2020 14:35:56

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-31T12:07:09', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4bfa4955-abb2-4a49-8d5c-31b0275a849d' User entered 'No (N)'	System	31 Oct 2020 17:07:14
	System	31 Oct 2020 17:07:14

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-10-31T12:07:11', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4bfa4955-abb2-4a49-8d5c-31b0275a849d' User entered '31 Oct 2020 12:07'	System	31 Oct 2020 17:07:14
	System	31 Oct 2020 17:07:14

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:35:56

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:35:56

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	30 Oct 2020 18:56:00
User entered 'Day 12'	System	30 Oct 2020 18:56:00

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-01T23:59:22', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dc1cb7ae-5c5b-4cb2-91f4-b478d98115f7'	System	02 Nov 2020 05:59:28
User entered 'No (N)'	System	02 Nov 2020 05:59:28

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-01T23:59:24', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dc1cb7ae-5c5b-4cb2-91f4-b478d98115f7' User entered '01 Nov 2020 23:59'	System	02 Nov 2020 05:59:28
	System	02 Nov 2020 05:59:28

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 18:56:00

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 18:56:00

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	31 Oct 2020 17:07:04
User entered 'Day 13'	System	31 Oct 2020 17:07:04

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-02T12:50:37', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f25e60d1-1e65-4be2-b870-711b9345107c' User entered 'No (N)'	System	02 Nov 2020 18:50:41
	System	02 Nov 2020 18:50:41

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-02T12:50:39', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f25e60d1-1e65-4be2-b870-711b9345107c' User entered '02 Nov 2020 12:50'	System	02 Nov 2020 18:50:41
	System	02 Nov 2020 18:50:41

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 17:07:04

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 17:07:04

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	02 Nov 2020 05:59:19
User entered 'Day 14'	System	02 Nov 2020 05:59:19

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-03T12:00:59', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f4d01229-f9c3-4617-9e18-d95743f92f39' User entered 'No (N)'	System	03 Nov 2020 18:01:09
	System	03 Nov 2020 18:01:09

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-03T12:01:04', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f4d01229-f9c3-4617-9e18-d95743f92f39' User entered '03 Nov 2020 12:01'	System	03 Nov 2020 18:01:09
	System	03 Nov 2020 18:01:09

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 05:59:19

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 05:59:19

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	02 Nov 2020 18:50:39
User entered 'Day 15'	System	02 Nov 2020 18:50:39

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-04T12:00:21', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '24f83fa0-e325-4a29-a4cb-c09f8688caf4' User entered 'No (N)'	System	04 Nov 2020 18:00:39
	System	04 Nov 2020 18:00:39

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-04T12:00:23', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '24f83fa0-e325-4a29-a4cb-c09f8688caf4' User entered '04 Nov 2020 12:00'	System	04 Nov 2020 18:00:39
	System	04 Nov 2020 18:00:39

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 18:50:39

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 18:50:39

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	03 Nov 2020 18:00:54
User entered 'Day 16'	System	03 Nov 2020 18:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 18:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 18:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
Data entry locked.	System	04 Nov 2020 18:00:27
User entered 'Day 17'	System	04 Nov 2020 18:00:27

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-06T15:30:27', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd748b922-6a7c-4099-860c-78d5a91a6d4c' User entered 'No (N)'	System	06 Nov 2020 21:30:33
	System	06 Nov 2020 21:30:33

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:01:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-06T15:30:29', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd748b922-6a7c-4099-860c-78d5a91a6d4c' User entered '06 Nov 2020 15:30'	System	06 Nov 2020 21:30:33
	System	06 Nov 2020 21:30:33

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 18:00:27

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 08:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:53:52
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 18:00:27

US3492243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:34:10

US3492243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:34:10

US3492243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:34:10

US3492243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:34:10

US3492243

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:33:57

US3492243

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'I'	System	29 Oct 2020 19:33:57

US3492243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:26:34

US3492243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:26:34

US3492243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:26:34

US3492243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:26:34

US3492243

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:26:40

US3492243

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'I'	System	05 Nov 2020 15:26:40

US3492243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:13:00

US3492243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:13:00

US3492243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:13:00

US3492243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:13:00

US3492243

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:13:28

US3492243

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'I'	System	12 Nov 2020 00:13:28

US3492243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:26

US3492243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:26

US3492243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[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 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:26

US3492243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'VISIT3'	System	19 Mar 2021 20:37:26

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	Andrea Wendrow (b) (4)	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered empty.	System	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered empty.	System	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered empty.	System	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered empty.	System	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered empty.	System	19 Mar 2021 20:37:37

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10

US3492243

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:45

US3492243

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:45

US3492243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:53

US3492243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:53

US3492243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:37:53

US3492243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered empty.	System	19 Mar 2021 20:37:53

US3492243

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	16 Dec 2020 17:34:48

US3492243

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered '1'	System	16 Dec 2020 17:34:48

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-30T18:21:40', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd1416ef4-c5bd-4e28-9901-35dc1f5dc7d1' User entered 'No (N)'	System	01 Dec 2020 00:21:58
	System	01 Dec 2020 00:21:58

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-30T18:21:49', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd1416ef4-c5bd-4e28-9901-35dc1f5dc7d1' User entered 'No (N)'	System	01 Dec 2020 00:21:58

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-11-30T18:21:52', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd1416ef4-c5bd-4e28-9901-35dc1f5dc7d1' User entered '30 Nov 2020 18:21:52'	System	01 Dec 2020 00:21:58
	System	01 Dec 2020 00:21:58

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-08T19:31:23', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a7209602-b62a-4ef5-98ee-14a0bf4e1f62'	System	09 Dec 2020 01:31:45
User entered 'No (N)'	System	09 Dec 2020 01:31:45

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-08T19:31:40', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a7209602-b62a-4ef5-98ee-14a0bf4e1f62'	System	09 Dec 2020 01:31:45
User entered 'No (N)'	System	09 Dec 2020 01:31:45

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-08T19:31:43', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'a7209602-b62a-4ef5-98ee-14a0bf4e1f62'	System	09 Dec 2020 01:31:45
User entered '08 Dec 2020 19:31:43'	System	09 Dec 2020 01:31:45

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-13T12:16:34', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '34520c4f-7f77-41d9-a5e0-93b3fade8464'	System	13 Dec 2020 18:16:43
User entered 'No (N)'	System	13 Dec 2020 18:16:43

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-13T12:16:37', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '34520c4f-7f77-41d9-a5e0-93b3fade8464'	System	13 Dec 2020 18:16:43
User entered 'No (N)'	System	13 Dec 2020 18:16:43

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-13T12:16:40', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '34520c4f-7f77-41d9-a5e0-93b3fade8464' User entered '13 Dec 2020 12:16:40'	System	13 Dec 2020 18:16:43
	System	13 Dec 2020 18:16:43

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-18T07:42:20', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd788706d-83cb-402e-a623-3d0f4766af0e' User entered 'No (N)'	System	18 Dec 2020 13:42:30
	System	18 Dec 2020 13:42:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-18T07:42:24', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd788706d-83cb-402e-a623-3d0f4766af0e' User entered 'No (N)'	System	18 Dec 2020 13:42:30
	System	18 Dec 2020 13:42:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-18T07:42:27', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd788706d-83cb-402e-a623-3d0f4766af0e' User entered '18 Dec 2020 07:42:27'	System	18 Dec 2020 13:42:30
	System	18 Dec 2020 13:42:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-25T08:03:21', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c8b833eb-1a30-4903-ab3b-6d978eb5be46' User entered 'No (N)'	System	25 Dec 2020 14:03:30
	System	25 Dec 2020 14:03:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-25T08:03:24', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c8b833eb-1a30-4903-ab3b-6d978eb5be46' User entered 'No (N)'	System	25 Dec 2020 14:03:30
	System	25 Dec 2020 14:03:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2020-12-25T08:03:27', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c8b833eb-1a30-4903-ab3b-6d978eb5be46' User entered '25 Dec 2020 08:03:27'	System	25 Dec 2020 14:03:30
	System	25 Dec 2020 14:03:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-01T00:02:32', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '518cf631-a0ea-41d2-a4af-d39c654b87e4'	System	01 Jan 2021 06:02:44
User entered 'No (N)'	System	01 Jan 2021 06:02:44

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-01T00:02:37', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '518cf631-a0ea-41d2-a4af-d39c654b87e4'	System	01 Jan 2021 06:02:44
User entered 'No (N)'	System	01 Jan 2021 06:02:44

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-01T00:02:40', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '518cf631-a0ea-41d2-a4af-d39c654b87e4' User entered '01 Jan 2021 00:02:40'	System	01 Jan 2021 06:02:44
	System	01 Jan 2021 06:02:44

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-08T07:16:44', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '7f957460-1e50-4ce5-af4a-c3d71e705565' User entered 'No (N)'	System	08 Jan 2021 13:16:58
	System	08 Jan 2021 13:16:58

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-08T07:16:50', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '7f957460-1e50-4ce5-af4a-c3d71e705565' User entered 'No (N)'	System	08 Jan 2021 13:16:58
	System	08 Jan 2021 13:16:58

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-08T07:16:53', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '7f957460-1e50-4ce5-af4a-c3d71e705565' User entered '08 Jan 2021 07:16:53'	System	08 Jan 2021 13:16:58
	System	08 Jan 2021 13:16:58

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-17T12:13:33', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '7bfa2618-89e2-4f47-9b86-db9f3811296b'	System	17 Jan 2021 18:13:43
User entered 'No (N)'	System	17 Jan 2021 18:13:43

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-17T12:13:37', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '7bfa2618-89e2-4f47-9b86-db9f3811296b'	System	17 Jan 2021 18:13:43
User entered 'No (N)'	System	17 Jan 2021 18:13:43

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-17T12:13:40', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '7bfa2618-89e2-4f47-9b86-db9f3811296b' User entered '17 Jan 2021 12:13:40'	System	17 Jan 2021 18:13:43
	System	17 Jan 2021 18:13:43

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-22T01:22:27', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e45b16f8-c66b-40d4-8f5c-ab3b70918010'	System	22 Jan 2021 07:22:38
User entered 'No (N)'	System	22 Jan 2021 07:22:38

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-22T01:22:33', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e45b16f8-c66b-40d4-8f5c-ab3b70918010'	System	22 Jan 2021 07:22:38
User entered 'No (N)'	System	22 Jan 2021 07:22:38

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-22T01:22:36', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e45b16f8-c66b-40d4-8f5c-ab3b70918010' User entered '22 Jan 2021 01:22:36'	System	22 Jan 2021 07:22:38
	System	22 Jan 2021 07:22:38

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-31T12:57:51', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f6361888-b4fc-409b-aec1-524a3a3d0033'	System	31 Jan 2021 18:58:00
User entered 'No (N)'	System	31 Jan 2021 18:58:00

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-31T12:57:54', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f6361888-b4fc-409b-aec1-524a3a3d0033'	System	31 Jan 2021 18:58:00
User entered 'No (N)'	System	31 Jan 2021 18:58:00

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-01-31T12:57:56', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f6361888-b4fc-409b-aec1-524a3a3d0033' User entered '31 Jan 2021 12:57:56'	System	31 Jan 2021 18:58:00

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-08T16:45:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dc93e2a1-f13f-429a-a041-3e795db03260'	System	08 Feb 2021 22:45:52
User entered 'No (N)'	System	08 Feb 2021 22:45:52

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-08T16:45:45', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dc93e2a1-f13f-429a-a041-3e795db03260'	System	08 Feb 2021 22:45:52
User entered 'No (N)'	System	08 Feb 2021 22:45:52

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-08T16:45:48', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dc93e2a1-f13f-429a-a041-3e795db03260' User entered '08 Feb 2021 16:45:48'	System	08 Feb 2021 22:45:52
	System	08 Feb 2021 22:45:52

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-12T07:08:55', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '37df6944-d447-405d-9f94-fab2eae0a997'	System	12 Feb 2021 13:09:11
User entered 'No (N)'	System	12 Feb 2021 13:09:11

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-12T07:09:06', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '37df6944-d447-405d-9f94-fab2eae0a997'	System	12 Feb 2021 13:09:11
User entered 'No (N)'	System	12 Feb 2021 13:09:11

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-12T07:09:08', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '37df6944-d447-405d-9f94-fab2eae0a997'	System	12 Feb 2021 13:09:11
User entered '12 Feb 2021 07:09:08'	System	12 Feb 2021 13:09:11

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-19T07:10:41', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f4e1ac6f-8dae-46c3-8331-9b04d16bdba5' User entered 'No (N)'	System	28 Feb 2021 18:05:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-19T07:10:43', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f4e1ac6f-8dae-46c3-8331-9b04d16bdba5'	System	28 Feb 2021 18:05:59
User entered 'No (N)'	System	28 Feb 2021 18:05:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-19T07:10:46', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'f4e1ac6f-8dae-46c3-8331-9b04d16bdba5' User entered '19 Feb 2021 07:10:46'	System	28 Feb 2021 18:05:59
	System	28 Feb 2021 18:05:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-28T12:02:44', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db314744-28bd-400c-9fb2-46d06142cb5a' User entered 'No (N)'	System	28 Feb 2021 18:06:30
	System	28 Feb 2021 18:06:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-28T12:02:53', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db314744-28bd-400c-9fb2-46d06142cb5a' User entered 'No (N)'	System	28 Feb 2021 18:06:30
	System	28 Feb 2021 18:06:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-28T12:02:56', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'db314744-28bd-400c-9fb2-46d06142cb5a'	System	28 Feb 2021 18:06:30
User entered '28 Feb 2021 12:02:56'	System	28 Feb 2021 18:06:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-03-05T06:27:59-06:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dc7a8830-b772-4aa6-a38a-38b5ba4b518c'	System	05 Mar 2021 12:28:10
User entered 'No (N)'	System	05 Mar 2021 12:28:10

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-03-05T06:28:05-06:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dc7a8830-b772-4aa6-a38a-38b5ba4b518c'	System	05 Mar 2021 12:28:10
User entered 'No (N)'	System	05 Mar 2021 12:28:10

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-03-05T06:28:08-06:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'dc7a8830-b772-4aa6-a38a-38b5ba4b518c' User entered '05 Mar 2021 06:28:08'	System	05 Mar 2021 12:28:10
	System	05 Mar 2021 12:28:10

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-03-19T07:15:42-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ed39d0d8-0af6-4fd6-899b-34258cf583fa'	System	19 Mar 2021 12:15:54
User entered 'No (N)'	System	19 Mar 2021 12:15:54

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-03-19T07:15:47-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ed39d0d8-0af6-4fd6-899b-34258cf583fa'	System	19 Mar 2021 12:15:54
User entered 'No (N)'	System	19 Mar 2021 12:15:54

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-03-19T07:15:50-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'ed39d0d8-0af6-4fd6-899b-34258cf583fa' User entered '19 Mar 2021 07:15:50'	System	19 Mar 2021 12:15:54
	System	19 Mar 2021 12:15:54

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-03-26T06:10:55-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'aba32924-b8fe-4db8-8b92-9089e812d91e'	System	26 Mar 2021 11:11:07
User entered 'No (N)'	System	26 Mar 2021 11:11:07

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-03-26T06:10:59-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'aba32924-b8fe-4db8-8b92-9089e812d91e'	System	26 Mar 2021 11:11:07
User entered 'No (N)'	System	26 Mar 2021 11:11:07

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-03-26T06:11:02-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'aba32924-b8fe-4db8-8b92-9089e812d91e' User entered '26 Mar 2021 06:11:02'	System	26 Mar 2021 11:11:07
	System	26 Mar 2021 11:11:07

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-02T07:00:14-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c8c03195-dc77-4c1a-92b3-425b5cee6156' User entered 'No (N)'	System	02 Apr 2021 12:00:30
	System	02 Apr 2021 12:00:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-02T07:00:21-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c8c03195-dc77-4c1a-92b3-425b5cee6156'	System	02 Apr 2021 12:00:30
User entered 'No (N)'	System	02 Apr 2021 12:00:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-02T07:00:24-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'c8c03195-dc77-4c1a-92b3-425b5cee6156' User entered '02 Apr 2021 07:00:24'	System	02 Apr 2021 12:00:30
	System	02 Apr 2021 12:00:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-09T03:49:23-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd32356fa-260e-419b-a6e0-6afc0805d03e'	System	09 Apr 2021 08:49:43
User entered 'No (N)'	System	09 Apr 2021 08:49:43

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-09T03:49:37-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd32356fa-260e-419b-a6e0-6afc0805d03e'	System	09 Apr 2021 08:49:43
User entered 'No (N)'	System	09 Apr 2021 08:49:43

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-09T03:49:40-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'd32356fa-260e-419b-a6e0-6afc0805d03e'	System	09 Apr 2021 08:49:43
User entered '09 Apr 2021 03:49:40'	System	09 Apr 2021 08:49:43

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-19T17:59:22-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0e3ea11a-99cd-492c-b1bf-b72b288586a0'	System	19 Apr 2021 22:59:30
User entered 'No (N)'	System	19 Apr 2021 22:59:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-19T17:59:26-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0e3ea11a-99cd-492c-b1bf-b72b288586a0'	System	19 Apr 2021 22:59:30
User entered 'No (N)'	System	19 Apr 2021 22:59:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-19T17:59:29-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '0e3ea11a-99cd-492c-b1bf-b72b288586a0' User entered '19 Apr 2021 17:59:29'	System	19 Apr 2021 22:59:30
	System	19 Apr 2021 22:59:30

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-23T07:31:19-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e1b33688-3254-4a96-b03e-7e119dbfbfd1'	System	23 Apr 2021 12:31:29
User entered 'No (N)'	System	23 Apr 2021 12:31:29

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-23T07:31:23-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e1b33688-3254-4a96-b03e-7e119dbfbfd1'	System	23 Apr 2021 12:31:29
User entered 'No (N)'	System	23 Apr 2021 12:31:29

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-04-23T07:31:26-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: 'e1b33688-3254-4a96-b03e-7e119dbfbfd1'	System	23 Apr 2021 12:31:29
User entered '23 Apr 2021 07:31:26'	System	23 Apr 2021 12:31:29

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-05-02T12:00:21-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4edfa96b-f962-455f-ae58-bbac3516e5b6'	System	02 May 2021 17:01:02
User entered 'No (N)'	System	02 May 2021 17:01:02

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

Have you been exposed to someone with 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 (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-05-02T12:00:27-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4edfa96b-f962-455f-ae58-bbac3516e5b6'	System	02 May 2021 17:01:02
User entered 'No (N)'	System	02 May 2021 17:01:02

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-05-02T12:00:30-05:00', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4edfa96b-f962-455f-ae58-bbac3516e5b6'	System	02 May 2021 17:01:02
User entered '02 May 2021 12:00:30'	System	02 May 2021 17:01:02

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 10:23:14

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:23:14
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 10:23:14

US3492243

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:01:25

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 13:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-28T12:03:06', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4a38d27b-8431-46e3-a514-249593427167'	System	28 Feb 2021 18:14:11
User entered 'No (N)'	System	28 Feb 2021 18:14:11

US3492243

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:01:25

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E94CF92B-1A01-4A47-B57B-B9884D8AFB44)', Time: '2021-02-28T12:03:09', User OID: 'PatientReportedOutcome (US3492243)', ODM File OID: '4a38d27b-8431-46e3-a514-249593427167' User entered '28 Feb 2021 12:03:09'	System	28 Feb 2021 18:14:11
	System	28 Feb 2021 18:14:11

US3492243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:09:36

US3492243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:09:36

US3492243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:09:36

US3492243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:09:36

US3492243

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:18:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:09:47

US3492243

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:42:10
User entered 'I'	System	16 Dec 2020 18:09:47

US3492243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:20:39

US3492243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:20:39

US3492243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:20:39

US3492243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:20:39

US3492243

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:21:01

US3492243

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User entered 'I'	System	19 Jan 2021 22:21:01

US3492243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:23:51

US3492243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:23:51

US3492243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:23:51

US3492243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:23:51

US3492243

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:24:01

US3492243

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User entered 'I'	System	18 Feb 2021 18:24:01

US3492243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:56

US3492243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:56

US3492243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:56

US3492243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:56

US3492243

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:57:07

US3492243

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:41:07
User entered 'I'	System	18 Mar 2021 13:57:07

US3492243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:12:36
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '20 Apr 2021'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:12:36
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered 'Clinic (Clinic)'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:12:36
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	20 Apr 2021 14:12:36

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:26:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '20 Apr 2021'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:26:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '09:20'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:26:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Apr 2021 09:20'	System	20 Apr 2021 14:26:44

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '96.8' F	Gizelle Alvarez (b) (4)	20 Apr 2021 14:26:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered 'Other (Other)'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:26:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered 'tympanic'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:26:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '63'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:26:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Apr 2021 14:26:44

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '16'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:26:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Apr 2021 14:26:44

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '127'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:26:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 14:26:44

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '84'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:26:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 14:26:44

US3492243

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:12:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '20 Apr 2021'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:12:44
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:24:08
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '20 Apr 2021'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:24:08
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered '09:19'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:24:08
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Apr 2021 09:19'	System	20 Apr 2021 14:24:08

US3492243

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	20 Apr 2021 14:12:54
	(b) (4)	

US3492243

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 14:12:54

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:25

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:25
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:54:21

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:25

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:25
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '09:45'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:54:21

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:25

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:25
User entered '18 Nov 2020 09:45'	System	18 Nov 2020 17:54:21

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:25

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:25
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:54:21

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:25

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:25
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:54:21

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '7 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '8 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '15 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '100'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered '%'	System	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '98'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered '%'	System	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	Diana Bahena (b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4)	
User entered '20 Nov 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	21 Nov 2020 23:44:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:07:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 22:07:02
User entered '19 Nov 2020' reason for change: Data Entry Error	Diana Bahena (b) (4)	20 Nov 2020 22:07:02
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:30:51
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '98' reason for change: Data Entry Error	Diana Bahena (b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered '%'	System	20 Nov 2020 22:07:02
User entered empty.	System	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '98.1' F reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 22:07:02
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '21 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '22 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered empty.	System	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '97'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
User entered '%'	System	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 08:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:45:12
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:01:25

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:01:25

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:01:25

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:57
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:42:27
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:29:19
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'done' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	23 Apr 2021 15:30:18
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	23 Apr 2021 15:30:05
Signature has been broken.	Andrea Wendrow (b) (4) (b) (4)	23 Apr 2021 15:30:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	23 Apr 2021 15:30:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:17:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 11:49:52
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:48:51
Query 'Data is required. Please complete.' answered with 'still pending as of 22Nov2020' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	22 Nov 2020 20:51:39
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 17:59:01
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:01:25

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:57
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:19
Signature has been broken.	Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:01:25

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:57
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:19
Signature has been broken.	Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:01:25

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:57
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:19
Signature has been broken.	Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User entered 'oropharyngeal' reason for change:	(b) (4)	
Data Entry Error	Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User signature succeeded.	(b) (4)	
	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:01:25

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:57
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:19
Signature has been broken.	Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:01:25

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:57
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:19
Signature has been broken.	Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User entered 'NorthShore Immediate Care Center'	(b) (4)	
reason for change: Data Entry Error	Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User signature succeeded.	(b) (4)	
	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:01:25

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:57
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:19
Signature has been broken.	Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Andrea Wendrow (b) (4)	23 Apr 2021 15:30:05
User signature succeeded.	(b) (4) Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:01:25

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:57
User entered '1'	System	23 Apr 2021 15:30:05
User entered '0'	System	16 Dec 2020 21:48:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:01:25

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Apr 2021 17:25:08

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
User entered empty.	Andrea Wendrow (b) (4)	26 Apr 2021 17:25:08

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	26 Apr 2021 17:25:08

US3492243

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
User entered empty.	Andrea Wendrow (b) (4)	26 Apr 2021 17:25:08

US3492243

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[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Apr 2021 17:25:08

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US3492243

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
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US3492243

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Apr 2021 17:25:08

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US3492243

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
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User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
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US3492243

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
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US3492243

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
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US3492243

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
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US3492243

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[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
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US3492243

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[High-Flow Oxygen?](#)

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US3492243

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
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US3492243

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US3492243

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[Mechanical Ventilation?](#)

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US3492243

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US3492243

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[ECMO?](#)

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US3492243

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[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:44:44
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
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US3492243

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[Evidence of Shock Requires
Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:15
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US3492243

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US3492243

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[Neurologic Dysfunction?](#)

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US3492243

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[Clinical Evidence](#)

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US3492243

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[Radiographical Evidence](#)

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:01:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '20 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:01:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '22 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:01:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:01:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:01:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:01:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57
	(b) (4)	

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:01:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	16 Dec 2020 21:46:57

US3492243

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,22NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:05:46
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,22NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:46:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,22NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 04:24:41
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:26:45

US3492243

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '18 Nov 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 00:26:45

US3492243

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Clinic (Clinic)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:26:45

US3492243

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
User entered 'SICKD1'	System	19 Nov 2020 00:26:45

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '18 Nov 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '10:00'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
User entered '18 Nov 2020 10:00'	System	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered missing code ND - Not Done.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:02
	(b) (4)	
DataPoint set to visible.	System	19 Nov 2020 00:26:45

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered missing code ND - Not Done.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:02
	(b) (4)	
DataPoint set to visible.	System	19 Nov 2020 00:26:45

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '98.8' F	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Other (Other)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'ear'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '77'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
User entered 'bpm'	System	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '18'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
User entered 'breaths/min'	System	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '148'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
User entered 'mmHg'	System	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '89'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
User entered 'mmHg'	System	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42

US3492243

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:15

US3492243

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:47
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '18 Nov 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:15

US3492243

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:01:25

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:28

US3492243

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:42
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 09:34:49
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'it is not missing in PPD. the accession number is 1F656988811 and we have reported. It is still in preclarus as shipped from site, another PPD error perhaps' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:44:25
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:57:43
User entered '18 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:28

US3492243

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

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:43:39

US3492243

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

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '28 Jan 2021'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:43:39

US3492243

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

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[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 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Clinic (Clinic)'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:43:39

US3492243

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

Form: Visit Date

Generated On: 10 Jun 2021 08:01:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 15:43:39

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '28 Jan 2021'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:44:05

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:53:15

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:44:05

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:53:15

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '28 Jan 2021'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:44:05

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'mRNA-1273 (mRNA-1273)'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:44:05

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'mRNA-1273 (mRNA-1273)'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:44:05

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'mRNA-1273 (mRNA-1273)'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:44:05

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:44:05

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered empty.	System	28 Jan 2021 15:44:05

US3492243

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

Form: Unblinding

Generated On: 10 Jun 2021 08:01:25

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered empty.	System	28 Jan 2021 15:44:05

US3492243

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:43:28

US3492243

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '28 Jan 2021'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:43:28

US3492243

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '09:33'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:43:28

US3492243

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered '28 Jan 2021 09:33'	System	28 Jan 2021 15:43:28

US3492243

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:43:12

US3492243

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '28 Jan 2021'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:43:12

US3492243

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:25

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '09:28'	Gizelle Alvarez (b) (4)	28 Jan 2021 15:43:12

US3492243

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:25

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:36
User entered '28 Jan 2021 09:28'	System	28 Jan 2021 15:43:12

US3492243

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:01:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:29
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 15). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:58:31
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 15). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 21:45:40
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 15). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:13:23
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:27:20

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 15:35:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 15:35:20
Data point term sent to Coder	System	05 Nov 2020 15:34:13
User entered 'fatigue'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:23:22
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with '-----This event is not within reactogenicity period.-----' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 21:18:08
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 04:04:36
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 21OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:23:11
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 21OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with '-----These symptoms were reported verbally and started after reactogenicity period was over. -----' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 21:19:59
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 21OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 04:04:43
User entered '1 Nov 2020'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
User entered empty.	System	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 00:15:15
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '3 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 00:15:15
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
User entered empty.	System	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (NONE)'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:15:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
User entered '0'	System	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58
User entered '0'	System	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:08:58

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 18:04:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 18:04:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 15:40:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 15:40:19
Data point term sent to Coder	System	05 Nov 2020 15:39:28
User entered 'muscle aches'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '1 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
User entered empty.	System	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 00:16:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '3 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 00:16:34
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
User entered empty.	System	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	12 Nov 2020 00:16:34
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:38:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 15:38:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	(b) (4), (b) (6)	05 Nov 2020 15:38:59
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:38:46
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
User entered '0'	System	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02
User entered '0'	System	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:09:02

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle soreness - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 03:50:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 03:50:57
Data point term sent to Coder	System	19 Nov 2020 00:33:45
User entered 'muscle soreness after workout'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '09 Oct 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
User entered empty.	System	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '14 Oct 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
User entered empty.	System	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:15:46
Query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:54:11
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 19:54:03
User opened query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:47:58
User entered 'None (NONE)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'soreness occurred after starting new workout routine'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
User entered '0'	System	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53
User entered '0'	System	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:19:53

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:28:25
User entered 'USA-US101-2020-mRNA-1273-P301000005'	System	19 Nov 2020 21:28:16
User entered 'New'	(b) (4), (b) (6)	19 Nov 2020 21:28:16

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'Per CDM: Per CCGs, positive Covid-19 AEs should be recorded as COVID-19 or SYMPTOMATIC COVID-19. Please review and update. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 06:30:17
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:34:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:34:24
Data point term sent to Coder	System	29 Jan 2021 21:33:24
Query 'Per CDM: Per CCGs, positive Covid-19 AEs should be recorded as COVID-19 or SYMPTOMATIC COVID-19. Please review and update. ' answered with 'done' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:33:01
Coding entries removed.	Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:32:52
User entered 'COVID-19' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:32:52
User opened query 'Per CDM: Per CCGs, positive Covid-19 AEs should be recorded as COVID-19 or SYMPTOMATIC COVID-19. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 20:25:53
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 00:56:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 00:56:50
Data point term sent to Coder	System	19 Nov 2020 00:40:51
User entered 'COVID-19 infection'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '07 Nov 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:51:04
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User closed query 'PV Query: End date was provided as 18 Nov 2020, however the subject still experienced the symptom of fatigue on 18 Nov 2020, please consider updating the end date to the first date the subject was symptom free. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:47:49
Query 'PV Query: End date was provided as 18 Nov 2020, however the subject still experienced the symptom of fatigue on 18 Nov 2020, please consider updating the end date to the first date the subject was symptom free. ' answered with 'updated' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 21:43:32
DataPoint Un-verified.	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 21:41:27
Signature has been broken.	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 21:41:27
User entered '19 Nov 2020' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 21:41:27
User opened query 'PV Query: End date was provided as 18 Nov 2020, however the subject still experienced the symptom of fatigue on 18 Nov 2020, please consider updating the end date to the first date the subject was symptom free. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 12:42:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:17:59
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Jan 2021 21:51:33
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	20 Jan 2021 21:51:33
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Jan 2021 21:51:04
User entered '18 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 21:51:04

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:39:57
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:21:46
User entered empty.	System	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
	(b) (4)	
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		11 Mar 2021 22:11:25
User entered 'Yes (Y)' reason for change: Per Query Michelle Agnoli Resolution	(b) (4)	11 Mar 2021 22:11:25
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	11 Mar 2021 17:30:46
DataPoint Un-verified.	Diana Bahena (b) (4)	11 Mar 2021 17:30:46
	(b) (4)	
Signature has been broken.	Diana Bahena (b) (4)	11 Mar 2021 17:30:46
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Diana Bahena (b) (4)	11 Mar 2021 17:30:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
	(b) (4)	
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'Please provide Investigator's rationale for seriousness criteria of Medically Significant.' (Site from Safety).	(b) (4)	
Query 'Please provide Investigator's rationale for seriousness criteria of Medically Significant.' answered with 'Medically significant since patient tested positive for COVID-19' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 14:34:12
User opened query 'Please provide Investigator's rationale for seriousness criteria of Medically Significant.' (Site from Safety).	Michelle Agnoli (b) (4)	29 Jan 2021 21:33:41
User entered 'I'	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 19:50:05
	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'PV Query: As the subject had already received both scheduled doses, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:40:59
Query 'PV Query: As the subject had already received both scheduled doses, please update the action taken with study drug from none to not applicable.' answered with 'corrected' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 16:53:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 16:53:00
User opened query 'PV Query: As the subject had already received both scheduled doses, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:21:13
User entered 'None (NONE)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 07:08:56
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'severity reported as mild' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 22:11:54
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 03:46:54
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:39:46
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 '-----Recovered.-----' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 21:52:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 21:51:33
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)	25 Nov 2020 20:21:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'PV Query: Please complete the symptom log from the event onset date (07 Nov 2020) to event end date (when symptoms resolved). ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:34:32
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 14:34:25
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 14:34:22
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 14:34:18
Query 'PV Query: Please complete the symptom log from the event onset date (07 Nov 2020) to event end date (when symptoms resolved). ' answered with 'Participant asymptomatic' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 22:02:34
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so. ' answered with 'patient denied any prior medical history on initial medical exam' (Site from Safety).	Michelle Agnoli (b) (4) (b) (4)	29 Jan 2021 21:42:20

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'illness visits performed per protocol. No medical or surgical or medication interventions completed' (Site from Safety).	Michelle Agnoli (b) (4)	29 Jan 2021 21:41:59
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'no medications reported 30 days prior to event. Patient tested due to child being positive. Patient's test was positive, but had no symptoms. ' (Site from Safety).	Michelle Agnoli (b) (4)	29 Jan 2021 21:39:46
User closed query 'PV Query: Was the subject tested for COVID-19 was reported as Yes, please provide results on 18 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:39:53
Query 'PV Query: Was the subject tested for COVID-19 was reported as Yes, please provide results on 18 Nov 2020.' answered with '-----Results of NP swab marked as "No" in folder " Covid-19 Assessments" under folder "COVID Diagnostic Test" for 18NOV2020.-----' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 21:55:08
User opened query 'PV Query: Please complete the symptom log from the event onset date (07 Nov 2020) to event end date (when symptoms resolved). ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 11:47:32
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 11:47:15
Query 'PV Query: Please provide the symptoms on the start date of the event (07 Nov 2020).' canceled (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 19:28:59

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:22:08
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:22:02
User opened query 'PV Query: Please provide the symptoms on the start date of the event (07 Nov 2020).' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:21:39
User opened query 'PV Query: Was the subject tested for COVID-19 was reported as Yes, please provide results on 18 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:21:23
User entered 'covid exposure from positive family member, began quarantine 06nov2020 c/o fatigue 07nov to 08Nov. took op covid test at outside facility 11Nov2020, positive result 13Nov2020. currently asymptomatic at D57 visit but changed to illness visit due to positive result.'	Andrea Wendrow (b) (4)	(b) (4) 19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 22:11:25
User entered '0'	System	11 Mar 2021 17:30:46
User entered '1'	System	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 21:48:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 21:48:44
Data point term sent to Coder	System	09 Apr 2021 21:47:58
User entered 'Fatigue'	Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User closed query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 May 2021 00:36:53
Query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' answered with 'updated ' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	29 Apr 2021 18:08:56
User opened query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 20:53:16
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:32:42
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
Reviewed for Data Management.	(b) (4), (b) (6)	26 Apr 2021 20:53:02
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4) (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '22 Oct 2020'	Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 13:57:17
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Diana Bahena (b) (4)	09 Apr 2021 21:47:21
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 21:47:06
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User entered empty.	System	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Diana Bahena (b) (4)	09 Apr 2021 21:49:14
User entered '18 Nov 2020'	(b) (4)	
	Diana Bahena (b) (4)	09 Apr 2021 21:47:06
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Apr 2021 13:57:19
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 13:57:19
User opened query 'Data is required. Please provide.' (Site from System).	Diana Bahena (b) (4)	09 Apr 2021 21:47:26
User entered empty.	(b) (4)	09 Apr 2021 21:47:06
	System	09 Apr 2021 21:47:06
	Diana Bahena (b) (4)	09 Apr 2021 21:47:06
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User entered empty.	System	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'No (N)'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '0'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '0'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '0'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered empty.	Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered empty.	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered empty.	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '0'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '0'	Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '0'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:25
Signature has been broken.	Marla Schwarber (b) (4)	29 Apr 2021 18:08:48
User entered 'Related (RELATED)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	29 Apr 2021 18:08:48
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'Not Related (NOT RELATED)'	Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'None (NONE)'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'I'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '0'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '0'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered empty.	(b) (4) Diana Bahena (b) (4)	09 Apr 2021 21:47:06
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered 'solicited AE beyond reactogenicity'	Diana Bahena (b) (4)	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User entered '0'	System	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01
User entered '0'	System	09 Apr 2021 21:47:06

US3492243

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:45:01

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:29
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1, 2, Pain at Injection Site and Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 08:59:51
Query 'Per DM CLR: Per Diary Dose 2 Day 1, 2, Pain at Injection Site and Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'confirmed with patient he took ibuprofen' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 22:03:50
Signature has been broken.	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 22:03:18
User entered 'Yes (Y)' reason for change: Per Query Resolution	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 22:03:18
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1, 2, Pain at Injection Site and Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:12:53

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site; Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:12:47
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1, Pain at Injection Site; Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:11:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'No (N)'	(b) (4) Nusirat Williams (b) (4)	23 Sep 2020 15:32:14

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Mar 2021 22:06:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 22:06:54
Data point term sent to Coder	System	11 Mar 2021 22:06:13
User entered 'ibuprofen'	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 22:06:09

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
	(b) (4)	
User entered 'No (N)'	Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE AND INJECTION SITE PAIN are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet 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 reactions of HEADACHE AND INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 22:24:23
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE AND INJECTION SITE PAIN are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet 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 reactions of HEADACHE AND INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'does not meet AE reporting criteria' (Site from DM).	Marla Schwarber (b) (4)	01 Apr 2021 19:21:38
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE AND INJECTION SITE PAIN are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet 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 reactions of HEADACHE AND INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 08:30:50

PRODUCTION RELEASE (v12.003
EAB) (1725)

2377 of 2521

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
User entered 'headache and injection site pain'	(b) (4) Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 22:06:09

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
	(b) (4)	
User entered '400'	Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
	(b) (4)	
User entered 'mg (mg)'	Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
	(b) (4)	
User entered empty.	Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
User entered 'as needed (PRN)'	(b) (4) Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
	(b) (4)	
User entered empty.	Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
	(b) (4)	
User entered 'Oral (ORAL)'	Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
	(b) (4)	
User entered empty.	Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
User entered '21 Oct 2020'	(b) (4) Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
	(b) (4)	
User entered '0'	Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
	(b) (4)	
User entered 'No (N)'	Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:55
	(b) (4)	
User entered '22 Oct 2020'	Michelle Agnoli (b) (4)	11 Mar 2021 22:06:09
	(b) (4)	

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Apr 2021 22:24:37
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 19:21:49
Signature has been broken.	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 19:21:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	01 Apr 2021 19:21:18
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 08:30:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:53:55
User entered 'No (N)'	Michelle Agnoli (b) (4) (b) (4)	11 Mar 2021 22:06:09

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 22:06:09

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 22:06:09

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 22:06:09

US3492243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:01:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
	(b) (4)	
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:32:21
	(b) (4)	

US3492243

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:01:25

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Data entered in error' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 18:26:59
User opened query 'Data is required. Please complete.' (Site from System).	Marla Schwarber (b) (4)	24 Nov 2020 16:37:01
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '13 Nov 2020'	System	24 Nov 2020 16:36:27
	Marla Schwarber (b) (4)	24 Nov 2020 16:36:27
	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:34:09

US3492243

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:01:25

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Data entered in error' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 18:27:00
User opened query 'Data is required. Please complete.' (Site from System).	Marla Schwarber (b) (4)	24 Nov 2020 16:37:03
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Due to SARS-COV-2 (COVID)'	System	24 Nov 2020 16:36:27
	Marla Schwarber (b) (4)	24 Nov 2020 16:36:27
	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:34:09

US3492243

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:34:09

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'USA-US101-2020-MRNA-1273-P301000005'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Richard'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Novak'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '808 S. Wood St'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Chicago'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'IL'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '60612'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:41:07
User entered 'US'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 16:07:39
User entered '5'	System	12 Mar 2021 15:59:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
	(b) (4)	
User entered '4'	System	01 Feb 2021 14:35:00
User entered '3'	System	21 Jan 2021 16:40:43
User entered '2'	System	01 Dec 2020 17:41:16
User entered '1'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'USA-US101-2020-MRNA-1273-P301000005'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Richard'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Novak'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '808 S. Wood St'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Chicago'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'IL'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '60612'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:41:07
User entered 'US'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 16:07:39
User entered '5'	System	12 Mar 2021 15:59:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
	(b) (4)	
User entered '4'	System	01 Feb 2021 14:35:00
User entered '3'	System	21 Jan 2021 16:40:43
User entered '2'	System	01 Dec 2020 17:41:16
User entered '1'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:01:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '19/Nov/2020 16:30'	(b) (4) System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:01:25

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)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:41:07
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'USA-US101-2020-MRNA-1273-P301000005'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Richard'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Novak'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '808 S. Wood St'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Chicago'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'IL'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '60612'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:41:07
User entered 'US'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 16:07:39
User entered '5'	System	12 Mar 2021 15:59:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
	(b) (4)	
User entered '4'	System	01 Feb 2021 14:35:00
User entered '3'	System	21 Jan 2021 16:40:43
User entered '2'	System	01 Dec 2020 17:41:16
User entered '1'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:01:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '01/Dec/2020 17:41'	(b) (4) System	01 Dec 2020 17:41:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:01:25

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)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 16:40:28
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 17:41:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'USA-US101-2020-MRNA-1273-P301000005'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Richard'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Novak'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '808 S. Wood St'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Chicago'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'IL'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '60612'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:41:07
User entered 'US'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 16:07:39
User entered '5'	System	12 Mar 2021 15:59:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
	(b) (4)	
User entered '4'	System	01 Feb 2021 14:35:00
User entered '3'	System	21 Jan 2021 16:40:43
User entered '2'	System	01 Dec 2020 17:41:16
User entered '1'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:01:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '21/Jan/2021 11:40'	(b) (4) System	21 Jan 2021 16:40:43

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:01:25

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)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 14:34:44
User entered 'I'	(b) (4), (b) (6)	21 Jan 2021 16:40:43

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'USA-US101-2020-MRNA-1273-P301000005'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Richard'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Novak'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '808 S. Wood St'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Chicago'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'IL'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '60612'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:41:07
User entered 'US'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 16:07:39
User entered '5'	System	12 Mar 2021 15:59:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
	(b) (4)	
User entered '4'	System	01 Feb 2021 14:35:00
User entered '3'	System	21 Jan 2021 16:40:43
User entered '2'	System	01 Dec 2020 17:41:16
User entered '1'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:01:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered '01/Feb/2021 14:34'	(b) (4) System	01 Feb 2021 14:35:00

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:01:25

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)	12 Mar 2021 15:46:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 14:35:00

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'USA-US101-2020-MRNA-1273-P301000005'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Richard'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Novak'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '808 S. Wood St'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Chicago'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'IL'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '60612'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:41:07
User entered 'US'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 16:07:39
User entered '5'	System	12 Mar 2021 15:59:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
	(b) (4)	
User entered '4'	System	01 Feb 2021 14:35:00
User entered '3'	System	21 Jan 2021 16:40:43
User entered '2'	System	01 Dec 2020 17:41:16
User entered '1'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:01:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered '12/Mar/2021 10:59'	(b) (4) System	12 Mar 2021 15:59:19

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:01:25

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)	12 Apr 2021 15:51:08
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:53:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:59:19

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'USA-US101-2020-MRNA-1273-P301000005'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'No (N)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Yes (Y)'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Richard'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Novak'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '808 S. Wood St'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'Chicago'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered 'IL'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:30:04
User entered '60612'	System	19 Nov 2020 21:28:16

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:46:45
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:41:07
User entered 'US'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	12 Apr 2021 16:07:39
User entered '5'	System	12 Mar 2021 15:59:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:17:59
	(b) (4)	
User entered '4'	System	01 Feb 2021 14:35:00
User entered '3'	System	21 Jan 2021 16:40:43
User entered '2'	System	01 Dec 2020 17:41:16
User entered '1'	System	19 Nov 2020 21:30:24

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:01:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
User entered '12/Apr/2021 16:07'	(b) (4) System	12 Apr 2021 16:07:39

US3492243

Folder: SAE USA-US101-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:01:25

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.	Richard Novak (b) (4)	26 Apr 2021 16:32:42
Un-reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:07:39
User entered '1' reason for change: Obvious Correction	(b) (4), (b) (6)	12 Apr 2021 16:07:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 16:07:24
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 15:51:18