

US3492243 (Prod: UIC Project WISH CRS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:31:38

All time stamps listed in this document are displayed in GMT

US3492243

Form: Participant Creation

Generated On: 26 Nov 2020 09:31:38

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

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 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:31:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:31:38

Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☒
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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

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.

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Folder: Screening

Form: Risk of Exposure

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify IT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

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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	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:38

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:38

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☐ Axillary ☐ Other ☒
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☐ Axillary ☐ Other ☒
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

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

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.

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:38

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:27 (24 HR)
Collection date and time (derived)	23 SEP 2020 10:27

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:38

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Yes ☐	
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

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☒
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)

Generated On: 26 Nov 2020 09:31:38

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☒
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

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Yes ☐	
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None ☐

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

FATIGUE

None ☐

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 09:31:38

TIMEPOINT

DAY 16

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

No ☐

Yes ☐

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

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 _____

US3492243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3492243

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

Was the sample collected?	Yes ☐
	No ☐

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3492243

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
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Date and time of submission	
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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 09:31:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 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: 26 Nov 2020 09:31:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 09:31:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 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: 26 Nov 2020 09:31:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 09:31:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
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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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 09:31:38

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:31:38

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:31:38

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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10 JUN 2022 00:01

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14 JUN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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17 JUN 2022 00:01

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21 JUN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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24 JUN 2022 00:01

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28 JUN 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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05 JUL 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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12 JUL 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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19 JUL 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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26 JUL 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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02 AUG 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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09 AUG 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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16 AUG 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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19 AUG 2022 00:01

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23 AUG 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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26 AUG 2022 00:01

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30 AUG 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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06 SEP 2022 23:59

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

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US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 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: 26 Nov 2020 09:31:38

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 09:31:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 09:31:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
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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: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:38

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	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☒
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	7 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	344 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

	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 (2)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	8 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	348 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

	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 (3)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	9 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	352 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

	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 (4)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	356 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

	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 (5)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	360 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

	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 (6)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	364 of 2145	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

	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 (7)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	368 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

	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 (8)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	372 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

	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 (9)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	376 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

	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 (10)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	380 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

	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 (11)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	384 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

	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 (12)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	388 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

	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)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	392 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

	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 (14)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☒
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	396 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:38

	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)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☒
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	400 of 2145	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

	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 (16)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☒
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	404 of 2145	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

	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 (17)

Generated On: 26 Nov 2020 09:31:38

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☒
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	408 of 2145	

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Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

	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: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:31:38

Date of Visit	18 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☐
Date of Test	18 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:31:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3492243

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:31:38

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3492243

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

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

US3492243

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

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: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

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 _____

US3492243

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3492243

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

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: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:31:38

Was Blood Sample Taken for Immunologic Assessment of	Yes	☐
SARS_COV-2 Infection?	No	☐
	NA (COVID-19 Negative)	☐

Date of Collection	
--------------------	--

US3492243

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:31:38

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)

Generated On: 26 Nov 2020 09:31:38

AEID	
Adverse event	FATIGUE
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)	1 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
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 ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	423 of 2145

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)

Generated On: 26 Nov 2020 09:31:38

AEID	
Adverse event	MUSCLE ACHES
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)	1 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
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 ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	425 of 2145

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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 (3)

Generated On: 26 Nov 2020 09:31:38

AEID	
Adverse event	FATIGUE
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)	7 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☒ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	ILLNESS VISIT PERFORMED 18NOV2020
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)

Generated On: 26 Nov 2020 09:31:38

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 ☐
Number of Days in ICU	
v6.020 DTW (1102)	
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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

AEID	USA-US101-2020-MRNA-1273-P30 1000005
Adverse event	COVID-19 INFECTION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	07 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	431 of 2145

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

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

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:31:38

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

Yes ☐

No ☒

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

US3492243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:31:38

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3492243

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

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

Generated On: 26 Nov 2020 09:31:38

SAEID	USA-US101-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
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)	1

US3492243

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:38

SAEID	USA-US101-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
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)	1
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

Audit

US3492243 (Prod: UIC Project WISH CRS)

US3492243

Form: Participant Creation

Generated On: 26 Nov 2020 09:31:38

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3492243'	RWS_ENDPOINT ENDPOINT (b) (4) 	23 Sep 2020 14:35:04

US3492243

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:24:51

US3492243

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '23 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	23 Sep 2020 14:35:05

US3492243

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:24:51

US3492243

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	23 Sep 2020 15:24:51

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	23 Sep 2020 14:35:07

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Age](#)

Audit	User	Time (GMT)
User entered '50'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '50'	System	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Nusirat Williams (b) (4)	23 Sep 2020 15:25:53
	(b) (4)	

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Ethnicity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[White](#)

Audit	User	Time (GMT)
User entered '1'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:38

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:25:53

US3492243

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '2020'	System	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:26:07

US3492243

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	23 Sep 2020 14:35:05

US3492243

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:26:13

US3492243

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	23 Sep 2020 15:26:13
	(b) (4)	

US3492243

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:31:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:26:52

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	23 Sep 2020 15:27:48
	(b) (4)	

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '09:53'	Nusirat Williams (b) (4)	23 Sep 2020 15:27:48
	(b) (4)	

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 09:53'	System	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

Height (xxx.x)

Audit	User	Time (GMT)
User entered '181.5' cm	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: 26 Nov 2020 09:31:38

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '113.4' kg	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: 26 Nov 2020 09:31:38

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4)	23 Sep 2020 15:27:48
	(b) (4)	

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4)	23 Sep 2020 15:27:48
	(b) (4)	

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4)	23 Sep 2020 15:27:48
	(b) (4)	

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4)	23 Sep 2020 15:27:48
	(b) (4)	

US3492243

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 15:27:48

US3492243

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:27:56

US3492243

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Nusirat Williams (b) (4)	23 Sep 2020 15:27:56
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

[Specify](#)

Audit	User	Time (GMT)
User entered 'IT'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '1'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4)	23 Sep 2020 15:28:38
	(b) (4)	

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:38

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:38

US3492243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:49

US3492243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:49

US3492243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:28:49

US3492243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	23 Sep 2020 15:28:49

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:38

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	23 Sep 2020 15:09:29

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:38

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '115300'	RWS_ENDPOINT ENDPOINT (b) (4) 	23 Sep 2020 15:09:29

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	23 Sep 2020 15:09:29

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:38

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:29:35

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:38

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:29:35

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:38

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:29:35

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:29:35

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:38

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:29:35

US3492243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:31:38

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:38

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Nusirat Williams (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '09:53'	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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	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: 26 Nov 2020 09:31:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'ear'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '12'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '161'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '94'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:38

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:30:58

US3492243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 09:31:38

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 16:14:17
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) (b) (4)	23 Sep 2020 16:14:17
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 15:30:58
User entered empty.	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: 26 Nov 2020 09:31:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data	Gizelle Alvarez (b) (4)	23 Sep 2020 16:14:17
Entry Error	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:31:38

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:31:08

US3492243

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:31:08

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Gizelle Alvarez (b) (4) (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:03'	Gizelle Alvarez (b) (4) (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:03'	System	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Gizelle Alvarez (b) (4) (b) (4)	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 16:12:52

US3492243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:31:29

US3492243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:31:29

US3492243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:27'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:31:29

US3492243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:38

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:30'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	23 Sep 2020 15:37:45
	(b) (4)	

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 15:37:45

US3492243

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:31:54

US3492243

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:31:54

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	23 Sep 2020 16:24:34
User entered '97.3'	System	23 Sep 2020 16:24:34

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 16:24:34
User entered '23 Sep 2020 11:24'	System	23 Sep 2020 16:24:34

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	23 Sep 2020 22:51:11
User entered 'Yes (Y)'	System	23 Sep 2020 22:51:11

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	23 Sep 2020 22:51:11
User entered '98.4'	System	23 Sep 2020 22:51:11

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	23 Sep 2020 22:51:11
User entered 'No (N)'	System	23 Sep 2020 22:51:11

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 22:51:11
User entered '23 Sep 2020 17:51'	System	23 Sep 2020 22:51:11

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:09:48
User entered 'Yes (Y)'	System	24 Sep 2020 17:09:48

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:09:48
User entered '98.6'	System	24 Sep 2020 17:09:48

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:09:48
User entered '24 Sep 2020 12:09'	System	24 Sep 2020 17:09:48

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:28:27
User entered 'Yes (Y)'	System	27 Sep 2020 02:28:27

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:28:27
User entered '97.9'	System	27 Sep 2020 02:28:27

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:28:27
User entered 'No (N)'	System	27 Sep 2020 02:28:27

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:28:27
User entered '26 Sep 2020 21:28'	System	27 Sep 2020 02:28:27

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:48:47
User entered 'Yes (Y)'	System	27 Sep 2020 19:48:47

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:48:47
User entered '98.3'	System	27 Sep 2020 19:48:47

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:44:17
User entered 'Yes (Y)'	System	28 Sep 2020 17:44:17

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:44:17
User entered '98.4'	System	28 Sep 2020 17:44:17

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:44:17
User entered '28 Sep 2020 12:44'	System	28 Sep 2020 17:44:17

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:07
User entered 'Yes (Y)'	System	29 Sep 2020 17:15:07

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:07
User entered '98.4'	System	29 Sep 2020 17:15:07

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:07
User entered '29 Sep 2020 12:15'	System	29 Sep 2020 17:15:07

US3492243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 22:51:32
User entered '23 Sep 2020 17:51'	System	23 Sep 2020 22:51:32

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:10:31
User entered 'No (N)'	System	24 Sep 2020 17:10:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:10:31
User entered 'No (N)'	System	24 Sep 2020 17:10:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:10:31
User entered 'None (1)'	System	24 Sep 2020 17:10:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:10:31
User entered '24 Sep 2020 12:10'	System	24 Sep 2020 17:10:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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' User entered 'Does not interfere with activity (2)'	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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:21:31
User entered 'No (N)'	System	25 Sep 2020 19:21:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:21:31
User entered 'No (N)'	System	25 Sep 2020 19:21:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:21:31
User entered 'None (1)'	System	25 Sep 2020 19:21:31

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:48:59
User entered '27 Sep 2020 14:48'	System	27 Sep 2020 19:48:59

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:44:38
User entered 'No (N)'	System	28 Sep 2020 17:44:38

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:44:38
User entered 'No (N)'	System	28 Sep 2020 17:44:38

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:44:38
User entered '28 Sep 2020 12:44'	System	28 Sep 2020 17:44:38

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:23
User entered '29 Sep 2020 12:15'	System	29 Sep 2020 17:15:23

US3492243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	23 Sep 2020 16:26:52
User entered 'None (0)'	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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'	System	23 Sep 2020 16:26:52
User entered 'None (0)'	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	23 Sep 2020 16:26:52
User entered 'None (0)'	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	23 Sep 2020 16:26:52
User entered 'None (0)'	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	23 Sep 2020 16:26:52
User entered 'None (0)'	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	23 Sep 2020 16:26:52
User entered 'No (N)'	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 16:26:52
User entered '23 Sep 2020 11:26'	System	23 Sep 2020 16:26:52

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	23 Sep 2020 22:52:07
User entered 'None (0)'	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	23 Sep 2020 22:52:07
User entered 'None (0)'	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	23 Sep 2020 22:52:07
User entered 'None (0)'	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	23 Sep 2020 22:52:07
User entered 'No (N)'	System	23 Sep 2020 22:52:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:11:13
User entered 'None (0)'	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:11:13
User entered 'None (0)'	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:11:13
User entered 'None (0)'	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:11:13
User entered 'None (0)'	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:11:13
User entered 'No (N)'	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:11:13
User entered '24 Sep 2020 12:11'	System	24 Sep 2020 17:11:13

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:22:07
User entered 'None (0)'	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:22:07
User entered 'None (0)'	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:22:07
User entered 'None (0)'	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:22:07
User entered 'None (0)'	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:22:07
User entered 'None (0)'	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:22:07
User entered 'No (N)'	System	25 Sep 2020 19:22:07

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:29:12
User entered 'None (0)'	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:29:12
User entered 'None (0)'	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:29:12
User entered 'None (0)'	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:29:12
User entered 'None (0)'	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:29:12
User entered 'None (0)'	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:29:12
User entered 'None (0)'	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 02:29:12
User entered 'No (N)'	System	27 Sep 2020 02:29:12

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:49:40
User entered 'None (0)'	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:49:40
User entered 'None (0)'	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:49:40
User entered 'None (0)'	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:49:40
User entered 'None (0)'	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:49:40
User entered 'None (0)'	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:49:40
User entered 'None (0)'	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:49:40
User entered 'No (N)'	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 19:49:40
User entered '27 Sep 2020 14:49'	System	27 Sep 2020 19:49:40

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:44:59
User entered 'None (0)'	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:44:59
User entered 'None (0)'	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:44:59
User entered 'None (0)'	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:44:59
User entered 'No (N)'	System	28 Sep 2020 17:44:59

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:42
User entered 'None (0)'	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:42
User entered 'None (0)'	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:42
User entered 'None (0)'	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:42
User entered 'None (0)'	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:42
User entered 'None (0)'	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:42
User entered 'None (0)'	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:42
User entered 'No (N)'	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:15:42
User entered '29 Sep 2020 12:15'	System	29 Sep 2020 17:15:42

US3492243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 21:40:20

US3492243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Addis Mekonnen (b) (4) (b) (4)	30 Sep 2020 21:40:20

US3492243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Addis Mekonnen (b) (4)	01 Oct 2020 14:08:39
User entered 'Contact Not Made (CONTACT NOT MADE)'	Addis Mekonnen (b) (4)	30 Sep 2020 21:40:20

US3492243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Addis Mekonnen (b) (4) (b) (4)	01 Oct 2020 14:09:36

US3492243

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 14:09:36

US3492243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 15:58:22

US3492243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 15:58:22

US3492243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 15:58:22

US3492243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 15:58:22

US3492243

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 15:58:27

US3492243

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:58:27

US3492243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	15 Oct 2020 15:45:35

US3492243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Gizelle Alvarez (b) (4) (b) (4)	15 Oct 2020 15:45:35

US3492243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Gizelle Alvarez (b) (4) (b) (4)	15 Oct 2020 15:45:35

US3492243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Gizelle Alvarez (b) (4) (b) (4)	15 Oct 2020 15:45:35

US3492243

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	15 Oct 2020 15:45:39

US3492243

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 15:45:39

US3492243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 14:35:30

US3492243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Oct 2020 14:35:30

US3492243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	21 Oct 2020 14:35:30

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) [REDACTED]	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:44:00
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) (b) (4)	21 Oct 2020 15:44:00
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 14:36:22
User entered empty.	(b) (4), (b) (6) (b) (4)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:23'	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36' C	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic'	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:38

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:44:00
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) (b) (4)	21 Oct 2020 15:44:00
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 14:36:22
User entered empty.	(b) (4), (b) (6) (b) (4)	21 Oct 2020 14:36:22

US3492243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020' reason for change: Data Entry Error	Nusirat Williams (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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '10:42' reason for change: Data Entry Error	Nusirat Williams (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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C reason for change: Data Entry Error	Nusirat Williams (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: 26 Nov 2020 09:31:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Nusirat Williams	(b) (4)	21 Oct 2020 15:44:00
Entry Error	(b) (4)	
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: 26 Nov 2020 09:31:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic' reason for change: Data Entry Error	Nusirat Williams (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: 26 Nov 2020 09:31:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '57' reason for change: Data Entry Error	Nusirat Williams (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: 26 Nov 2020 09:31:38

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Nusirat Williams (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: 26 Nov 2020 09:31:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124' reason for change: Data Entry Error	Nusirat Williams (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: 26 Nov 2020 09:31:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '84' reason for change: Data Entry Error	Nusirat Williams (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: 26 Nov 2020 09:31:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 14:36:35

US3492243

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 14:36:35

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	21 Oct 2020 15:40:40
	(b) (4)	

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Nusirat Williams (b) (4)	21 Oct 2020 15:40:40
	(b) (4)	

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:35'	Nusirat Williams (b) (4)	21 Oct 2020 15:40:40
	(b) (4)	

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 15:40:40

US3492243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	21 Oct 2020 15:40:47

US3492243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	21 Oct 2020 15:40:47

US3492243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	21 Oct 2020 15:40:47

US3492243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 15:40:47

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4) (b) (4)	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:38

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:31:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	21 Oct 2020 15:40:53
	(b) (4)	

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4)	21 Oct 2020 15:40:53
	(b) (4)	

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	21 Oct 2020 15:40:53
	(b) (4)	

US3492243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 15:40:53

US3492243

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	21 Oct 2020 15:40:57

US3492243

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 15:40:57

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:55:36
User entered 'Yes (Y)'	System	21 Oct 2020 15:55:36

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:55:36
User entered '97.3'	System	21 Oct 2020 15:55:36

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:55:36
User entered 'No (N)'	System	21 Oct 2020 15:55:36

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:55:36
User entered '21 Oct 2020 10:55'	System	21 Oct 2020 15:55:36

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	22 Oct 2020 09:28:17
User entered 'Yes (Y)'	System	22 Oct 2020 09:28:17

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	22 Oct 2020 09:28:17
User entered '98.6'	System	22 Oct 2020 09:28:17

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Oct 2020 09:28:17
User entered '22 Oct 2020 04:28'	System	22 Oct 2020 09:28:17

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:01:51
User entered 'Yes (Y)'	System	22 Oct 2020 17:01:51

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:01:51
User entered '99.1'	System	22 Oct 2020 17:01:51

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:01:51
User entered 'No (N)'	System	22 Oct 2020 17:01:51

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:01:51
User entered '22 Oct 2020 12:01'	System	22 Oct 2020 17:01:51

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:22:46
User entered 'Yes (Y)'	System	24 Oct 2020 15:22:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:22:46
User entered '98.2'	System	24 Oct 2020 15:22:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:22:46
User entered 'No (N)'	System	24 Oct 2020 15:22:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:22:46
User entered '24 Oct 2020 10:22'	System	24 Oct 2020 15:22:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	24 Oct 2020 17:00:54
User entered 'Yes (Y)'	System	24 Oct 2020 17:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	24 Oct 2020 17:00:54
User entered '98.3'	System	24 Oct 2020 17:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	24 Oct 2020 17:00:54
User entered 'No (N)'	System	24 Oct 2020 17:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	26 Oct 2020 16:30:46
User entered 'Yes (Y)'	System	26 Oct 2020 16:30:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	26 Oct 2020 16:30:46
User entered '98.3'	System	26 Oct 2020 16:30:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	26 Oct 2020 16:30:46
User entered '26 Oct 2020 11:30'	System	26 Oct 2020 16:30:46

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	27 Oct 2020 15:45:39
User entered '98.5'	System	27 Oct 2020 15:45:39

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	27 Oct 2020 15:45:39
User entered '27 Oct 2020 10:45'	System	27 Oct 2020 15:45:39

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	28 Oct 2020 12:15:52
User entered 'Yes (Y)'	System	28 Oct 2020 12:15:52

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	28 Oct 2020 12:15:52
User entered 'No (N)'	System	28 Oct 2020 12:15:52

US3492243

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:55:56
User entered 'No (N)'	System	21 Oct 2020 15:55:56

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	22 Oct 2020 09:28:51
User entered 'No (N)'	System	22 Oct 2020 09:28:51

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:02:09
User entered 'No (N)'	System	22 Oct 2020 17:02:09

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:02:09
User entered 'No (N)'	System	22 Oct 2020 17:02:09

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:02:09
User entered 'None (1)'	System	22 Oct 2020 17:02:09

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:02:09
User entered '22 Oct 2020 12:01'	System	22 Oct 2020 17:02:09

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:21:19
User entered 'None (1)'	System	24 Oct 2020 15:21:19

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:21:19
User entered 'None (1)'	System	24 Oct 2020 15:21:19

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:21:19
User entered '24 Oct 2020 10:21'	System	24 Oct 2020 15:21:19

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Oct 2020 17:01:11
User entered '24 Oct 2020 12:01'	System	24 Oct 2020 17:01:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	26 Oct 2020 16:31:00
User entered 'No (N)'	System	26 Oct 2020 16:31:00

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	26 Oct 2020 16:31:00
User entered 'No (N)'	System	26 Oct 2020 16:31:00

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Oct 2020 12:16:11
User entered '28 Oct 2020 07:16'	System	28 Oct 2020 12:16:11

US3492243

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:56:22
User entered 'None (0)'	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:56:22
User entered 'None (0)'	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:56:22
User entered 'None (0)'	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:56:22
User entered 'None (0)'	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:56:22
User entered 'None (0)'	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:56:22
User entered 'No (N)'	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Oct 2020 15:56:22
User entered '21 Oct 2020 10:56'	System	21 Oct 2020 15:56:22

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	22 Oct 2020 09:29:28
User entered 'None (0)'	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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'	System	22 Oct 2020 09:29:28
User entered 'None (0)'	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	22 Oct 2020 09:29:28
User entered 'No (N)'	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	22 Oct 2020 09:29:28
User entered '22 Oct 2020 04:29'	System	22 Oct 2020 09:29:28

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:02:56
User entered 'None (0)'	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:02:56
User entered 'None (0)'	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	22 Oct 2020 17:02:56
User entered 'No (N)'	System	22 Oct 2020 17:02:56

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:23:13
User entered 'None (0)'	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:23:13
User entered 'None (0)'	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:23:13
User entered 'None (0)'	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:23:13
User entered 'No (N)'	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	24 Oct 2020 15:23:13
User entered '24 Oct 2020 10:23'	System	24 Oct 2020 15:23:13

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	26 Oct 2020 16:31:19
User entered '26 Oct 2020 11:31'	System	26 Oct 2020 16:31:19

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	27 Oct 2020 15:46:07
User entered 'None (0)'	System	27 Oct 2020 15:46:07

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

HEADACHE

Audit	User	Time (GMT)
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'	System	28 Oct 2020 12:16:41
User entered 'None (0)'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	28 Oct 2020 12:16:41
User entered 'None (0)'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	28 Oct 2020 12:16:41
User entered 'None (0)'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	28 Oct 2020 12:16:41
User entered 'None (0)'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

CHILLS

Audit	User	Time (GMT)
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'	System	28 Oct 2020 12:16:41
User entered 'None (0)'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	28 Oct 2020 12:16:41
User entered 'No (N)'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	28 Oct 2020 12:16:41
User entered '28 Oct 2020 07:16'	System	28 Oct 2020 12:16:41

US3492243

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
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'	System	30 Oct 2020 14:35:56
User entered 'Some interference with activity (2)'	System	30 Oct 2020 14:35:56

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
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'	System	31 Oct 2020 17:07:04
User entered 'No interference with activity (1)'	System	31 Oct 2020 17:07:04

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 05:59:19
User entered '01 Nov 2020 23:59'	System	02 Nov 2020 05:59:19

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 18:50:39
User entered '02 Nov 2020 12:50'	System	02 Nov 2020 18:50:39

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	03 Nov 2020 18:00:54
User entered '03 Nov 2020 12:00'	System	03 Nov 2020 18:00:54

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
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'	System	06 Nov 2020 21:30:29
User entered 'None (0)'	System	06 Nov 2020 21:30:29

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 09:31:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	06 Nov 2020 21:30:29
User entered '06 Nov 2020 15:30'	System	06 Nov 2020 21:30:29

US3492243

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	28 Oct 2020 19:32:29
User entered 'No (N)'	System	28 Oct 2020 19:32:29

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	30 Oct 2020 14:36:02
User entered 'No (N)'	System	30 Oct 2020 14:36:02

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	30 Oct 2020 14:36:02
User entered '30 Oct 2020 09:35'	System	30 Oct 2020 14:36:02

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	30 Oct 2020 18:56:09
User entered 'No (N)'	System	30 Oct 2020 18:56:09

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	30 Oct 2020 18:56:09
User entered '30 Oct 2020 13:56'	System	30 Oct 2020 18:56:09

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	31 Oct 2020 17:07:14
User entered 'No (N)'	System	31 Oct 2020 17:07:14

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	31 Oct 2020 17:07:14
User entered '31 Oct 2020 12:07'	System	31 Oct 2020 17:07:14

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 05:59:28
User entered '01 Nov 2020 23:59'	System	02 Nov 2020 05:59:28

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	02 Nov 2020 18:50:41
User entered 'No (N)'	System	02 Nov 2020 18:50:41

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	02 Nov 2020 18:50:41
User entered '02 Nov 2020 12:50'	System	02 Nov 2020 18:50:41

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	03 Nov 2020 18:01:09
User entered 'No (N)'	System	03 Nov 2020 18:01:09

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	03 Nov 2020 18:01:09
User entered '03 Nov 2020 12:01'	System	03 Nov 2020 18:01:09

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	04 Nov 2020 18:00:39
User entered 'No (N)'	System	04 Nov 2020 18:00:39

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	04 Nov 2020 18:00:39
User entered '04 Nov 2020 12:00'	System	04 Nov 2020 18:00:39

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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'	System	06 Nov 2020 21:30:33
User entered 'No (N)'	System	06 Nov 2020 21:30:33

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:31:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	06 Nov 2020 21:30:33
User entered '06 Nov 2020 15:30'	System	06 Nov 2020 21:30:33

US3492243

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:31:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 19:34:10

US3492243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 19:34:10

US3492243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Oct 2020 19:34:10

US3492243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 19:34:10

US3492243

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 19:33:57

US3492243

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 19:33:57

US3492243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:26:34

US3492243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 15:26:34

US3492243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Nov 2020 15:26:34

US3492243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:26:34

US3492243

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:26:40

US3492243

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:26:40

US3492243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 00:13:00

US3492243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 00:13:00

US3492243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Nov 2020 00:13:00

US3492243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 00:13:00

US3492243

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 00:13:28

US3492243

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 00:13:28

US3492243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[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: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:38

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:54:21

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:38

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '09:45'	(b) (4), (b) (6)	18 Nov 2020 17:54:21

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	18 Nov 2020 17:54:21

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 17:54:21

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '7 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:02

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '8 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '9 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:23

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 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: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:35

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:55:49

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:03

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:14

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:37

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:56:48

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:57:09

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.8' F	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 17:58:25

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)' reason for change:	Diana Bahena (b) (4)	20 Nov 2020 22:07:02
Data Entry Error	(b) (4)	
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: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
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).	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 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: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 21:30:51

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.1' F 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: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' 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 (15)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:33

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:21:45

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Date](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.8' F	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:31:38

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Nov 2020 19:24:32

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:31:38

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:31:38

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:31:38

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'still pending as of 22Nov2020' (Site from System).	Andrea Wendrow (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: 26 Nov 2020 09:31:38

[Date of Test](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:31:38

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:31:38

[Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Covid-19 Assessment 18 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:31:38

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:59:01

US3492243

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:26:45

US3492243

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	19 Nov 2020 00:26:45

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:00'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Height (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:02
DataPoint set to visible.	(b) (4) System	19 Nov 2020 00:26:45

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

Weight (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:02
DataPoint set to visible.	(b) (4) System	19 Nov 2020 00:26:45

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:02
	(b) (4)	

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'ear'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '18'	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:02
	(b) (4)	

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '148'	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:02
	(b) (4)	

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '89'	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:02
	(b) (4)	

US3492243

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 00:28:02

US3492243

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:15

US3492243

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 00:28:15
	(b) (4)	

US3492243

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:31:38

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:31:38

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:28:28

US3492243

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:31:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:27:20

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Adverse event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[None](#)

Audit	User	Time (GMT)
User entered '1'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(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: 26 Nov 2020 09:31:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 15:33:35

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Adverse event](#)

Audit	User	Time (GMT)
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) (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) (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) (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) (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: 26 Nov 2020 09:31:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '1 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(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: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:38:59
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: 26 Nov 2020 09:31:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 15:38:46

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Adverse event](#)

Audit	User	Time (GMT)
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)	18 Nov 2020 18:02:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 18:02:11
Data point term sent to Coder	System	18 Nov 2020 18:02:08
User entered 'Fatigue'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '7 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 18:01:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 18:01:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 18:01:47
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 18:01:35
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Illness visit performed 18Nov2020'	(b) (4), (b) (6)	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:31:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 18:01:35

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Adverse event](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '09 Oct 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Severity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[None](#)

Audit	User	Time (GMT)
User entered '1'	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Outcome](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 00:33:11
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Narrative](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:31:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 00:33:11

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Adverse event](#)

Audit	User	Time (GMT)
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)	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)	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)	19 Nov 2020 00:40:33
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered '07 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Start time \(00:00-23:59\)](#)

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: 26 Nov 2020 09:31:38

[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: 26 Nov 2020 09:31:38

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

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: 26 Nov 2020 09:31:38

[End time \(00:00-23:59\)](#)

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: 26 Nov 2020 09:31:38

[AE End 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: 26 Nov 2020 09:31:38

[Severity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Number of Days in ICU](#)

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: 26 Nov 2020 09:31:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[None](#)

Audit	User	Time (GMT)
User entered '1'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33
	(b) (4)	

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Wendrow (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Narrative](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 00:40:33

US3492243

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:31:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 00:40:33

US3492243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:31:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	23 Sep 2020 15:32:14

US3492243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:31:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 18:26:59
Query 'Data is required. Please complete.' answered with 'Data entered in error' (Site from System).	Marla Schwarber (b) (4)	24 Nov 2020 16:37:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	24 Nov 2020 16:36:27
User entered '13 Nov 2020'	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: 26 Nov 2020 09:31:38

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 18:27:00
Query 'Data is required. Please complete.' answered with 'Data entered in error' (Site from System).	Marla Schwarber (b) (4)	24 Nov 2020 16:37:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	24 Nov 2020 16:36:27
User entered 'Due to SARS-COV-2 (COVID)'	Marla Schwarber (b) (4)	24 Nov 2020 16:36:27
	(b) (4), (b) (6)	23 Nov 2020 20:34:09

US3492243

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:31:38

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

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 09:31:38

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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

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Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:31:38

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:31:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '19/Nov/2020 16:30'	System	19 Nov 2020 21:30:24

US3492243

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:38

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 entered '1'	(b) (4), (b) (6)	19 Nov 2020 21:30:24