

US3492064 (Prod: UIC Project WISH CRS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:28:29

All time stamps listed in this document are displayed in GMT

US3492064

Form: Participant Creation

Generated On: 26 Nov 2020 09:28:29

[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 09:28:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 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 09:28:29

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
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 09:28:29

Date of Informed Consent (<i>dd MMM yyyy</i>)	04 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 09:28:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:28:29

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

Condition	CORNEAL ABRASION
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

Condition	RIGHT LOWER EXTREMITY WEAKNESS
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	04 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:04 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 11:04
Height (<i>xxx.x</i>)	176.9 cm
Weight (<i>xxx.x</i>)	96.3 kg
BMI (<i>xxx.x</i>)	30.77306 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 09:28:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 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

Generated On: 26 Nov 2020 09:28:29

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐
	No ☒
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐
	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐
	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐
	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐
	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐
	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☒
	No ☐
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐
	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐
	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐
	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐
	No ☒
Other	Yes ☐
	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	True
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)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 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 09:28:29

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 145868

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 09:28:29

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 09:28:29

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)	04 SEP 2020
Time of assessment (00:00-23:59)	11:04 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 11:04
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	NOT SPECIFIED
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 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 09:28:29

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)	04 SEP 2020
Time of assessment (00:00-23:59)	13:29 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 13:29
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 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 09:28:29

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)	4 SEP 2020
What was the treatment time? (00:00-23:59)	12:58 (24 HR)
Treatment Date and Time (derived)	4 SEP 2020 12:58
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 09:28:29

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

04 SEP 2020

Collection time (*00:00-23:59*)

12:17 (24 HR)

Collection date and time (derived)

04 SEP 2020 12:17

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:29

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:30	04 SEP 2020 12:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

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 09:28:29

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.3 °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 04 SEP 2020 13:44

PC Open Date & Time 04 SEP 2020 13:18

PC Close Date & Time 04 SEP 2020 15:48

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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 96.0 °F

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

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

PC Time Stamp	05 SEP 2020 09:39
PC Open Date & Time	04 SEP 2020 16:43
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 08:48

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 07:44

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

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

97.5 °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

08 SEP 2020 06:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

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

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 05:49

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

10 SEP 2020 05:46

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 06:22

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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

04 SEP 2020 13:46

PC Open Date & Time

04 SEP 2020 13:18

PC Close Date & Time

04 SEP 2020 15:48

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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

05 SEP 2020 09:40

PC Open Date & Time

04 SEP 2020 16:43

PC Close Date & Time

05 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

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

06 SEP 2020 08:48

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

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

07 SEP 2020 07:45

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

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

08 SEP 2020 06:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

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

09 SEP 2020 05:50

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

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

10 SEP 2020 05:47

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

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

11 SEP 2020 06:22

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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

No ☐

Yes ☒

PC Time stamp	04 SEP 2020 13:47
PC Open Date & Time	04 SEP 2020 13:18
PC Close Date & Time	04 SEP 2020 15:48

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 09:41
PC Open Date & Time	04 SEP 2020 16:43
PC Close Date & Time	05 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	06 SEP 2020 08:50
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	07 SEP 2020 07:46
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	08 SEP 2020 06:04
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	09 SEP 2020 05:51
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	10 SEP 2020 05:48
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	11 SEP 2020 06:23
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 SEP 2020 08:26

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 13 SEP 2020 05:40

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

14 SEP 2020 07:13

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 15 SEP 2020 06:25

PC Open Date & Time 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 SEP 2020 06:00

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 17 SEP 2020 09:37

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 SEP 2020 08:17

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 SEP 2020 07:19

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 SEP 2020 09:17

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 21 SEP 2020 06:00

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 12 SEP 2020 08:27

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 SEP 2020 05:41

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

14 SEP 2020 07:13

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 15 SEP 2020 06:25

PC Open Date & Time 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 SEP 2020 06:01

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 SEP 2020 09:37

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 SEP 2020 08:17

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 19 SEP 2020 07:19

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 SEP 2020 09:17

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	12 SEP 2020 08:27
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	13 SEP 2020 05:41
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	14 SEP 2020 07:14
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 SEP 2020 06:26
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	16 SEP 2020 06:01
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	17 SEP 2020 09:37
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	18 SEP 2020 08:17
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	19 SEP 2020 07:19
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	20 SEP 2020 09:17
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3492064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 10:34
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	NOT SPECIFIED
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 12:50
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	NOT SPECIFIED
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3492064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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)	2 OCT 2020
What was the treatment time? (00:00-23:59)	12:20 (24 HR)
Treatment Date and Time (derived)	2 OCT 2020 12:20
Which arm was used to give treatment?	Left Arm ☐
	Right Arm ☒
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3492064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:29

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	02 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:50 (24 HR)
Collection date and time (derived)	02 OCT 2020 10:50

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:29

Collection date (<i>dd MMM yyyy</i>)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:00	02 OCT 2020 11:00
Nasopharyngeal Swab 2	No		

US3492064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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

97.5 °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 02 OCT 2020 12:57

PC Open Date & Time 02 OCT 2020 12:40

PC Close Date & Time 02 OCT 2020 15:10

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 02 OCT 2020 16:05

PC Close Date & Time 03 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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 03 OCT 2020 14:31

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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 04 OCT 2020 12:22

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 13:12

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

06 OCT 2020 17:33

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

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

98.2 °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

07 OCT 2020 14:09

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

08 OCT 2020 16:15

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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

02 OCT 2020 12:57

PC Open Date & Time

02 OCT 2020 12:40

PC Close Date & Time

02 OCT 2020 15:10

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 OCT 2020 16:05

PC Close Date & Time

03 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

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

03 OCT 2020 14:31

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

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

04 OCT 2020 12:23

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

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

05 OCT 2020 13:13

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

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

06 OCT 2020 17:33

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

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

07 OCT 2020 14:11

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

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

08 OCT 2020 16:17

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 12:59
PC Open Date & Time	02 OCT 2020 12:40
PC Close Date & Time	02 OCT 2020 15:10

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 16:05

PC Close Date & Time

03 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	03 OCT 2020 14:32
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	04 OCT 2020 12:25
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	05 OCT 2020 13:14
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	06 OCT 2020 17:34
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	07 OCT 2020 14:11
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

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 ☒

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

Yes ☐	
PC Time stamp	08 OCT 2020 16:18
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 09 OCT 2020 17:26

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp	10 OCT 2020 14:04

PC Open Date & Time	10 OCT 2020 12:00

PC Close Date & Time	11 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 OCT 2020 14:23

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp	12 OCT 2020 12:00

PC Open Date & Time	12 OCT 2020 12:00

PC Close Date & Time	13 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 13 OCT 2020 17:39

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 14 OCT 2020 13:19

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 15 OCT 2020 12:00

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 OCT 2020 12:06

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 17 OCT 2020 12:37

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 OCT 2020 12:01

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 OCT 2020 17:26

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	10 OCT 2020 14:04

PC Open Date & Time	10 OCT 2020 12:00

PC Close Date & Time	11 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 11 OCT 2020 14:23

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	12 OCT 2020 12:00

PC Open Date & Time	12 OCT 2020 12:00

PC Close Date & Time	13 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 OCT 2020 17:39

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 14 OCT 2020 13:19

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	15 OCT 2020 12:01

PC Open Date & Time	15 OCT 2020 12:00

PC Close Date & Time	16 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 OCT 2020 12:06

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 OCT 2020 12:37

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	18 OCT 2020 12:01

PC Open Date & Time	18 OCT 2020 12:00

PC Close Date & Time	19 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 19 OCT 2020 13:17

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 OCT 2020 13:32

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 21 OCT 2020 13:21

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 OCT 2020 12:00

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 23 OCT 2020 12:00

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 24 OCT 2020 12:24

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 25 OCT 2020 15:25

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 27 OCT 2020 14:51

PC Open Date & Time 27 OCT 2020 12:00

PC Close Date & Time 28 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 29 OCT 2020 08:45

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 29 OCT 2020 12:04

PC Open Date & Time 29 OCT 2020 12:00

PC Close Date & Time 30 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 29

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 30 OCT 2020 14:03

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 31 OCT 2020 16:10

PC Open Date & Time 31 OCT 2020 12:00

PC Close Date & Time 01 NOV 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 31

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 NOV 2020 16:31

PC Open Date & Time 01 NOV 2020 12:00

PC Close Date & Time 02 NOV 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	09 OCT 2020 17:27
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 OCT 2020 14:04
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	11 OCT 2020 14:23
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	12 OCT 2020 12:00
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	13 OCT 2020 17:39
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	14 OCT 2020 13:19
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 OCT 2020 12:01
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	16 OCT 2020 12:06
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 16

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

No ☒

Yes ☐

PC Time stamp

17 OCT 2020 12:37

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 17

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

No ☒

Yes ☐

PC Time stamp

18 OCT 2020 12:01

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	19 OCT 2020 13:18
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	20 OCT 2020 13:32
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	21 OCT 2020 13:21
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	22 OCT 2020 12:00
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	23 OCT 2020 12:00
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	24 OCT 2020 12:24
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	25 OCT 2020 15:25
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 25

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	27 OCT 2020 14:51
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	29 OCT 2020 08:45
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	29 OCT 2020 12:04
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	30 OCT 2020 14:03
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐ Yes ☒
PC Time stamp	31 OCT 2020 16:10
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 31

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

No ☐

Yes ☒

PC Time stamp

01 NOV 2020 16:31

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3492064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492064

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3492064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

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)	

US3492064

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:29

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.

US3492064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:29

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)	

US3492064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	04 NOV 2020 06:17:50
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 NOV 2020 12:02:58
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 03:47:58
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 08:14:44
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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10 FEB 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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17 FEB 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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 FEB 2022 00:01

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24 FEB 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

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03 MAR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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10 MAR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 MAR 2022 00:01

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17 MAR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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24 MAR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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°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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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 APR 2022 00:01

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21 APR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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09 JUN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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23 JUN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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30 JUN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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14 JUL 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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21 JUL 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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28 JUL 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	08 SEP 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3492064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492064

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:29

Date of Contact	02 NOV 2020
Time of Contact	12:00
Date and Time of Contact (derived)	02 NOV 2020 12:00
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 ☒

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:28:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3492064

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:28:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

AEID	
Adverse event	GENERALIZED 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)	05 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	23 SEP 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)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

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)	_____

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

AEID	
Adverse event	JOINT 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)	4 SEP 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

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

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)	

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

AEID	USA-US101-2020-MRNA-1273-P30 1000004
Adverse event	CEREBROVASCULAR ACCIDENT
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	31 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	11 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	True
Hospital Admission Date (dd MMM yyyy)	31 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	11 NOV 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	11
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

Persistent or significant disability or incapacity	True
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	False
Concomitant Medication	True
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:	RIGHT LOWER EXTREMITY WEAKNESS
Narrative	

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

PARTICIPANT PHONED STUDY SITE ON 02NOV2020 TO REPORT THAT HAD BEEN ADMITTED ON 31OCT2020 TO OUTSIDE HOSPITAL AFTER HAVING "MASSIVE HEADACHE AND THE FEELING OF LOSS OF USE OF RIGHT LEG" ON THAT BEGAN 30OCT2020. ADDITIONALLY REPORTED THAT WERE DIAGNOSED COVID-19 POSITIVE UPON ADMISSION. AWAITING FURTHER DETAILS OF HOSPITALIZATION	
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)	1

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

AEID	
Adverse event	ASYMPTOMATIC 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)	31 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	11 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	
v6.020 DTW (1102)	
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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

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	SUBJECT HOSPITALIZED FOR CVA (SEE OTHER AE) AND AT TIME OF ADMISSION A COVID RT-PCR WAS FOUND TO BE POSITIVE. SUBJECT REMAINED ASYMPTOMATIC THROUGHOUT HOSPITALIZATION
Serious Adverse Event Derived (CSA Programming Field Only)	0

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:28:29

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

Yes ☒

No ☐

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

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	CHOLESTEROL - HYPERLIPIDEMIA
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES
Dose per administration	850
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		02 OCT 2019
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	VITAMIN B-12
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	1000
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	VITAMIN C
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	ERYTHROMYCIN
Prophylaxis	Yes ☐ No ☒
Indication	RUNNY EYE ISSUE - CORNEAL ABRASION
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	APPLICATION
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	RIGHT EYE AT BEDTIME
Route of administration	Oral ☐ Topical ☒ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	TAMSULOSIN
Prophylaxis	Yes ☐ No ☒
Indication	BPH
Dose per administration	0.4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	ASPIRIN
Prophylaxis	Yes ☒ No ☐
Indication	ASCVD PROPHYLAXIS
Dose per administration	81
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	CLOPIDROGREL
Prophylaxis	Yes ☒ No ☐
Indication	ASCVD PROPHYLAXIS
Dose per administration	75
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	HEPARIN
Prophylaxis	Yes ☒ No ☐
Indication	THROMBUS PROPHYLAXIS
Dose per administration	5000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNITS
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	MIRALAX
Prophylaxis	Yes ☒ No ☐
Indication	PREVENT CONSTIPATION
Dose per administration	17
Dose unit	mg ☐ ug ☐ mL ☐ g ☒ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

Name of Medication	SENOKOT
Prophylaxis	Yes ☒ No ☐
Indication	PREVENT CONSTIPATION
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3492064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:28:29

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3492064

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:28:29

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

US3492064

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:28:29

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 ☐

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

SAEID	USA-US101-2020-MRNA-1273-P301000004
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)	2

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:28:29

SAEID	USA-US101-2020-MRNA-1273-P301000004
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)	2
Date of submission (Pre-filled from custom function)	03/NOV/2020 20:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:28:29

SAEID	USA-US101-2020-MRNA-1273-P301000004
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)	2
Date of submission (Pre-filled from custom function)	20/NOV/2020 18:29
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

US3492064 (Prod: UIC Project WISH CRS)

US3492064

Form: Participant Creation

Generated On: 26 Nov 2020 09:28:29

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3492064'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Sep 2020 15:54:55

US3492064

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 17:52:42

US3492064

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Sep 2020 15:54:56

US3492064

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 17:52:42

US3492064

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	04 Sep 2020 17:52:42

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Sep 2020 15:54:57

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[Age](#)

Audit	User	Time (GMT)
User entered '59'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '59'	System	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[White](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[Black](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:29

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '04 Sep 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4)	10 Nov 2020 20:54:55
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '2020'	System	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:29

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)' reason for change:	Marla Schwarber (b) (4)	25 Sep 2020 17:21:52
Data Entry Error	(b) (4)	
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 17:54:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 17:54:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 17:54:08
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 17:54:01
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Sep 2020 15:54:56

US3492064

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 17:55:31

US3492064

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 17:55:31

US3492064

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:28:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:35:24

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Eye injuries NEC, PT: Corneal abrasion, LLT: Corneal abrasion - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 15:37:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 15:37:51
Data point term sent to Coder	System	08 Sep 2020 15:36:54
User entered 'corneal abrasion'	(b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'un May 2020'	(b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'May 2020'	System	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:37:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:37:51
Data point term sent to Coder	System	08 Sep 2020 15:36:56
User entered 'type 2 diabetes'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '2018'	System	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle weakness conditions, PT: Muscular weakness, LLT: Lower extremities weakness of - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:13:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:13:47
Data point term sent to Coder	System	08 Sep 2020 15:41:08
User entered 'right lower extremity weakness'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	(b) (4), (b) (6)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '2017'	System	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 15:44:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 15:44:17
Data point term sent to Coder	System	08 Sep 2020 15:43:11
User entered 'hyperlipidemia'	(b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'un UNK 2020'	(b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '11:04'	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:04'	System	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '176.9' cm	(b) (4), (b) (6)	08 Sep 2020 15:45:03
DataPoint set to visible.	System	04 Sep 2020 17:55:31

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '96.3' kg	(b) (4), (b) (6)	08 Sep 2020 15:45:03
DataPoint set to visible.	System	04 Sep 2020 17:55:31

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '30.77306'	System	08 Sep 2020 15:45:03
DataPoint set to visible.	System	04 Sep 2020 17:55:31

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	08 Sep 2020 15:45:03
DataPoint set to visible.	System	04 Sep 2020 17:55:31

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:45:20

US3492064

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 15:45:20

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:29

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 17:54:24

US3492064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '04 Sep 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4)	10 Nov 2020 20:54:18
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 17:54:24

US3492064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 17:54:24

US3492064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	04 Sep 2020 17:54:24

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Sep 2020 17:09:22

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:29

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User entered '145868'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Sep 2020 17:09:22

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Sep 2020 17:09:22

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:29

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)'	(b) (4), (b) (6)	04 Sep 2020 17:55:04

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 17:55:04

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 17:55:04

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 17:55:04

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:29

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 17:55:04

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:24:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:24:36

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:29

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 14:34:54
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:35:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:35:29
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:13:38
User entered '176.9' cm	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:29

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:35:29
User entered '96.3' kg	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:29

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 14:34:54
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:35:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:35:29
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:13:38
User entered '176.9' cm	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:29

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:35:29
User entered '96.3' kg	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '11:04'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:04'	System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'not specified'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:29

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 14:34:54
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:35:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:35:29
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:13:38
User entered '176.9' cm	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:29

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	12 Oct 2020 15:35:29
change Data Entry Error		
User entered '96.3' kg	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '13:29'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '04 Sep 2020 13:29'	System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '117'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '75'	(b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:47:28

US3492064

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 15:47:28

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '12:58'	(b) (4), (b) (6)	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 12:58'	System	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:47:58

US3492064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 15:47:58

US3492064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:17'	(b) (4), (b) (6)	08 Sep 2020 15:47:58

US3492064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:17'	System	08 Sep 2020 15:47:58

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:29

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:30'	(b) (4), (b) (6)	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:30'	System	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:29

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:48:32

US3492064

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 15:48:32

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:44:11', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9dc527b1-ca1c-45c3-b299-794fff7c04f4'	System	04 Sep 2020 18:43:48
User entered 'Yes (Y)'	System	04 Sep 2020 18:43:48

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:44:31', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9dc527b1-ca1c-45c3-b299-794fff7c04f4'	System	04 Sep 2020 18:43:48
User entered '98.3'	System	04 Sep 2020 18:43:48

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:44:42', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9dc527b1-ca1c-45c3-b299-794fff7c04f4'	System	04 Sep 2020 18:43:48
User entered 'No (N)'	System	04 Sep 2020 18:43:48

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:44:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9dc527b1-ca1c-45c3-b299-794fff7c04f4'	System	04 Sep 2020 18:43:48
User entered '04 Sep 2020 13:44'	System	04 Sep 2020 18:43:48

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 13:18'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:48'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:38:39', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5705f4b2-6149-49a1-bc9b-8de07c30f97a'	System	05 Sep 2020 14:37:55
User entered 'Yes (Y)'	System	05 Sep 2020 14:37:55

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:38:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5705f4b2-6149-49a1-bc9b-8de07c30f97a'	System	05 Sep 2020 14:37:55
User entered '96.0'	System	05 Sep 2020 14:37:55

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:38:53', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5705f4b2-6149-49a1-bc9b-8de07c30f97a'	System	05 Sep 2020 14:37:55
User entered 'No (N)'	System	05 Sep 2020 14:37:55

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:39:03', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5705f4b2-6149-49a1-bc9b-8de07c30f97a'	System	05 Sep 2020 14:37:55
User entered '05 Sep 2020 09:39'	System	05 Sep 2020 14:37:55

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 16:43'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 2'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:47:35', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a676701d-28fb-4212-b13b-1187273c0359'	System	06 Sep 2020 13:46:50
User entered 'Yes (Y)'	System	06 Sep 2020 13:46:50

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:47:48', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a676701d-28fb-4212-b13b-1187273c0359'	System	06 Sep 2020 13:46:50
User entered '96.7'	System	06 Sep 2020 13:46:50

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:47:54', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a676701d-28fb-4212-b13b-1187273c0359'	System	06 Sep 2020 13:46:50
User entered 'No (N)'	System	06 Sep 2020 13:46:50

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:48:01', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a676701d-28fb-4212-b13b-1187273c0359'	System	06 Sep 2020 13:46:50
User entered '06 Sep 2020 08:48'	System	06 Sep 2020 13:46:50

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 3'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:44:13', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cf4c8b29-ab9b-4b40-9007-cf02e5ef0d38'	System	07 Sep 2020 12:43:31
User entered 'Yes (Y)'	System	07 Sep 2020 12:43:31

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:44:30', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cf4c8b29-ab9b-4b40-9007-cf02e5ef0d38'	System	07 Sep 2020 12:43:31
User entered '97.8'	System	07 Sep 2020 12:43:31

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:44:33', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cf4c8b29-ab9b-4b40-9007-cf02e5ef0d38'	System	07 Sep 2020 12:43:31
User entered 'No (N)'	System	07 Sep 2020 12:43:31

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:44:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cf4c8b29-ab9b-4b40-9007-cf02e5ef0d38'	System	07 Sep 2020 12:43:31
User entered '07 Sep 2020 07:44'	System	07 Sep 2020 12:43:31

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 4'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:02:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd38a1138-0406-4291-91b0-fa3e63838d72'	System	08 Sep 2020 11:01:11
User entered 'Yes (Y)'	System	08 Sep 2020 11:01:11

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:02:07', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd38a1138-0406-4291-91b0-fa3e63838d72'	System	08 Sep 2020 11:01:11
User entered '97.5'	System	08 Sep 2020 11:01:11

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:02:11', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd38a1138-0406-4291-91b0-fa3e63838d72'	System	08 Sep 2020 11:01:11
User entered 'No (N)'	System	08 Sep 2020 11:01:11

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:02:20', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd38a1138-0406-4291-91b0-fa3e63838d72'	System	08 Sep 2020 11:01:11
User entered '08 Sep 2020 06:02'	System	08 Sep 2020 11:01:11

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 5'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:49:33', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9f84283d-ed6b-4c3c-bfce-46b72506eb9c'	System	09 Sep 2020 10:48:51
User entered 'Yes (Y)'	System	09 Sep 2020 10:48:51

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:49:45', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9f84283d-ed6b-4c3c-bfce-46b72506eb9c'	System	09 Sep 2020 10:48:51
User entered '95.8'	System	09 Sep 2020 10:48:51

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:49:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9f84283d-ed6b-4c3c-bfce-46b72506eb9c'	System	09 Sep 2020 10:48:51
User entered 'No (N)'	System	09 Sep 2020 10:48:51

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:49:59', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9f84283d-ed6b-4c3c-bfce-46b72506eb9c'	System	09 Sep 2020 10:48:51
User entered '09 Sep 2020 05:49'	System	09 Sep 2020 10:48:51

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 6'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:46:17', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'fb6d4b4f-70e1-42cb-9f43-1e56831798ca'	System	10 Sep 2020 10:45:20
User entered 'Yes (Y)'	System	10 Sep 2020 10:45:20

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:46:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'fb6d4b4f-70e1-42cb-9f43-1e56831798ca'	System	10 Sep 2020 10:45:20
User entered '97.5'	System	10 Sep 2020 10:45:20

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:46:26', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'fb6d4b4f-70e1-42cb-9f43-1e56831798ca'	System	10 Sep 2020 10:45:20
User entered 'No (N)'	System	10 Sep 2020 10:45:20

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:46:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'fb6d4b4f-70e1-42cb-9f43-1e56831798ca' User entered '10 Sep 2020 05:46'	System	10 Sep 2020 10:45:20
	System	10 Sep 2020 10:45:20

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 7'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:21:43', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8fd1af1e-0c31-4705-ab71-bf297da0aa1d'	System	11 Sep 2020 11:20:52
User entered 'Yes (Y)'	System	11 Sep 2020 11:20:52

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:21:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8fd1af1e-0c31-4705-ab71-bf297da0aa1d'	System	11 Sep 2020 11:20:52
User entered '96.7'	System	11 Sep 2020 11:20:52

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:21:57', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8fd1af1e-0c31-4705-ab71-bf297da0aa1d'	System	11 Sep 2020 11:20:52
User entered 'No (N)'	System	11 Sep 2020 11:20:52

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:22:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8fd1af1e-0c31-4705-ab71-bf297da0aa1d'	System	11 Sep 2020 11:20:52
User entered '11 Sep 2020 06:22'	System	11 Sep 2020 11:20:52

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-04T13:45:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f3701fae-6089-4a2b-a5d6-c472f9af439b'	System	04 Sep 2020 18:45:07
User entered 'None (1)'	System	04 Sep 2020 18:45:07

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:45:36', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f3701fae-6089-4a2b-a5d6-c472f9af439b'	System	04 Sep 2020 18:45:07
User entered 'No (N)'	System	04 Sep 2020 18:45:07

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:45:54', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f3701fae-6089-4a2b-a5d6-c472f9af439b'	System	04 Sep 2020 18:45:07
User entered 'No (N)'	System	04 Sep 2020 18:45:07

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-04T13:46:05', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f3701fae-6089-4a2b-a5d6-c472f9af439b'	System	04 Sep 2020 18:45:07
User entered 'None (1)'	System	04 Sep 2020 18:45:07

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:46:15', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f3701fae-6089-4a2b-a5d6-c472f9af439b'	System	04 Sep 2020 18:45:07
User entered '04 Sep 2020 13:46'	System	04 Sep 2020 18:45:07

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 13:18'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:48'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-05T09:40:03', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a671c082-8870-4494-9721-c1fc34becd7f'	System	05 Sep 2020 14:39:05
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 14:39:05

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:39:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a671c082-8870-4494-9721-c1fc34becd7f'	System	05 Sep 2020 14:39:05
User entered 'No (N)'	System	05 Sep 2020 14:39:05

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:39:40', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a671c082-8870-4494-9721-c1fc34becd7f'	System	05 Sep 2020 14:39:05
User entered 'No (N)'	System	05 Sep 2020 14:39:05

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-05T09:39:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a671c082-8870-4494-9721-c1fc34becd7f'	System	05 Sep 2020 14:39:05
User entered 'None (1)'	System	05 Sep 2020 14:39:05

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:40:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a671c082-8870-4494-9721-c1fc34becd7f'	System	05 Sep 2020 14:39:05
User entered '05 Sep 2020 09:40'	System	05 Sep 2020 14:39:05

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 16:43'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 2'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-06T08:48:17', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'aa574958-fb6b-4870-af9e-e88ca47f295a'	System	06 Sep 2020 13:47:38
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 13:47:38

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:48:21', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'aa574958-fb6b-4870-af9e-e88ca47f295a'	System	06 Sep 2020 13:47:38
User entered 'No (N)'	System	06 Sep 2020 13:47:38

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:48:27', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'aa574958-fb6b-4870-af9e-e88ca47f295a'	System	06 Sep 2020 13:47:38
User entered 'No (N)'	System	06 Sep 2020 13:47:38

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-06T08:48:34', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'aa574958-fb6b-4870-af9e-e88ca47f295a'	System	06 Sep 2020 13:47:38
User entered 'None (1)'	System	06 Sep 2020 13:47:38

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:48:46', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'aa574958-fb6b-4870-af9e-e88ca47f295a'	System	06 Sep 2020 13:47:38
User entered '06 Sep 2020 08:48'	System	06 Sep 2020 13:47:38

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 3'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-07T07:44:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '17a37952-b7bb-4036-a11b-0094a852f0d8'	System	07 Sep 2020 12:44:12
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 12:44:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:44:52', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '17a37952-b7bb-4036-a11b-0094a852f0d8'	System	07 Sep 2020 12:44:12
User entered 'No (N)'	System	07 Sep 2020 12:44:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:45:06', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '17a37952-b7bb-4036-a11b-0094a852f0d8'	System	07 Sep 2020 12:44:12
User entered 'No (N)'	System	07 Sep 2020 12:44:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-07T07:45:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '17a37952-b7bb-4036-a11b-0094a852f0d8'	System	07 Sep 2020 12:44:12
User entered 'None (1)'	System	07 Sep 2020 12:44:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:45:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '17a37952-b7bb-4036-a11b-0094a852f0d8'	System	07 Sep 2020 12:44:12
User entered '07 Sep 2020 07:45'	System	07 Sep 2020 12:44:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 4'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-08T06:02:46', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3db8ce51-8601-4f8d-9600-676c3b89e2e4'	System	08 Sep 2020 11:02:00
User entered 'None (1)'	System	08 Sep 2020 11:02:00

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:02:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3db8ce51-8601-4f8d-9600-676c3b89e2e4'	System	08 Sep 2020 11:02:00
User entered 'No (N)'	System	08 Sep 2020 11:02:00

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:03:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3db8ce51-8601-4f8d-9600-676c3b89e2e4'	System	08 Sep 2020 11:02:00
User entered 'No (N)'	System	08 Sep 2020 11:02:00

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-08T06:03:03', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3db8ce51-8601-4f8d-9600-676c3b89e2e4'	System	08 Sep 2020 11:02:00
User entered 'None (1)'	System	08 Sep 2020 11:02:00

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:03:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3db8ce51-8601-4f8d-9600-676c3b89e2e4'	System	08 Sep 2020 11:02:00
User entered '08 Sep 2020 06:03'	System	08 Sep 2020 11:02:00

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 5'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-09T05:50:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'bd39a6d2-d997-4740-838d-33607ada4330'	System	09 Sep 2020 10:49:36
User entered 'None (1)'	System	09 Sep 2020 10:49:36

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:50:15', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'bd39a6d2-d997-4740-838d-33607ada4330'	System	09 Sep 2020 10:49:36
User entered 'No (N)'	System	09 Sep 2020 10:49:36

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:50:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'bd39a6d2-d997-4740-838d-33607ada4330'	System	09 Sep 2020 10:49:36
User entered 'No (N)'	System	09 Sep 2020 10:49:36

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-09T05:50:28', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'bd39a6d2-d997-4740-838d-33607ada4330'	System	09 Sep 2020 10:49:36
User entered 'None (1)'	System	09 Sep 2020 10:49:36

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:50:45', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'bd39a6d2-d997-4740-838d-33607ada4330'	System	09 Sep 2020 10:49:36
User entered '09 Sep 2020 05:50'	System	09 Sep 2020 10:49:36

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 6'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-10T05:46:51', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c86991a0-4a4f-447e-94ca-b12a0d4a5cdf'	System	10 Sep 2020 10:45:56
User entered 'None (1)'	System	10 Sep 2020 10:45:56

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:46:54', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c86991a0-4a4f-447e-94ca-b12a0d4a5cdf'	System	10 Sep 2020 10:45:56
User entered 'No (N)'	System	10 Sep 2020 10:45:56

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:46:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c86991a0-4a4f-447e-94ca-b12a0d4a5cdf'	System	10 Sep 2020 10:45:56
User entered 'No (N)'	System	10 Sep 2020 10:45:56

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-10T05:47:02', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c86991a0-4a4f-447e-94ca-b12a0d4a5cdf'	System	10 Sep 2020 10:45:56
User entered 'None (1)'	System	10 Sep 2020 10:45:56

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:47:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c86991a0-4a4f-447e-94ca-b12a0d4a5cdf'	System	10 Sep 2020 10:45:56
User entered '10 Sep 2020 05:47'	System	10 Sep 2020 10:45:56

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 7'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-11T06:22:10', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e2c947b-6e08-46e2-9796-9de785314eec'	System	11 Sep 2020 11:21:12
User entered 'None (1)'	System	11 Sep 2020 11:21:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:22:13', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e2c947b-6e08-46e2-9796-9de785314eec'	System	11 Sep 2020 11:21:12
User entered 'No (N)'	System	11 Sep 2020 11:21:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:22:17', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e2c947b-6e08-46e2-9796-9de785314eec'	System	11 Sep 2020 11:21:12
User entered 'No (N)'	System	11 Sep 2020 11:21:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-11T06:22:21', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e2c947b-6e08-46e2-9796-9de785314eec'	System	11 Sep 2020 11:21:12
User entered 'None (1)'	System	11 Sep 2020 11:21:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:22:26', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e2c947b-6e08-46e2-9796-9de785314eec'	System	11 Sep 2020 11:21:12
User entered '11 Sep 2020 06:22'	System	11 Sep 2020 11:21:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:46:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '576ae109-9b59-420d-9c9e-a7d3c7226ac6'	System	04 Sep 2020 18:46:43
User entered 'None (0)'	System	04 Sep 2020 18:46:43

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:46:44', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '576ae109-9b59-420d-9c9e-a7d3c7226ac6'	System	04 Sep 2020 18:46:43
User entered 'None (0)'	System	04 Sep 2020 18:46:43

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:46:54', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '576ae109-9b59-420d-9c9e-a7d3c7226ac6'	System	04 Sep 2020 18:46:43
User entered 'None (0)'	System	04 Sep 2020 18:46:43

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:47:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '576ae109-9b59-420d-9c9e-a7d3c7226ac6'	System	04 Sep 2020 18:46:43
User entered 'None (0)'	System	04 Sep 2020 18:46:43

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:47:22', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '576ae109-9b59-420d-9c9e-a7d3c7226ac6'	System	04 Sep 2020 18:46:43
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	04 Sep 2020 18:46:43

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:47:36', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '576ae109-9b59-420d-9c9e-a7d3c7226ac6'	System	04 Sep 2020 18:46:43
User entered 'None (0)'	System	04 Sep 2020 18:46:43

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-04T13:47:42', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '576ae109-9b59-420d-9c9e-a7d3c7226ac6'	System	04 Sep 2020 18:46:43
User entered 'Yes (Y)'	System	04 Sep 2020 18:46:43

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-04T13:47:51', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '576ae109-9b59-420d-9c9e-a7d3c7226ac6'	System	04 Sep 2020 18:46:43
User entered '04 Sep 2020 13:47'	System	04 Sep 2020 18:46:43

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 13:18'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:48'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:40:37', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ef732fd8-719e-467b-8b82-0133751ef6e0'	System	05 Sep 2020 14:40:29
User entered 'No interference with activity (1)'	System	05 Sep 2020 14:40:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:40:45', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ef732fd8-719e-467b-8b82-0133751ef6e0'	System	05 Sep 2020 14:40:29
User entered 'None (0)'	System	05 Sep 2020 14:40:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:40:53', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ef732fd8-719e-467b-8b82-0133751ef6e0'	System	05 Sep 2020 14:40:29
User entered 'None (0)'	System	05 Sep 2020 14:40:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:41:15', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ef732fd8-719e-467b-8b82-0133751ef6e0'	System	05 Sep 2020 14:40:29
User entered 'None (0)'	System	05 Sep 2020 14:40:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:41:18', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ef732fd8-719e-467b-8b82-0133751ef6e0'	System	05 Sep 2020 14:40:29
User entered 'None (0)'	System	05 Sep 2020 14:40:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:41:21', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ef732fd8-719e-467b-8b82-0133751ef6e0'	System	05 Sep 2020 14:40:29
User entered 'None (0)'	System	05 Sep 2020 14:40:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-05T09:41:26', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ef732fd8-719e-467b-8b82-0133751ef6e0'	System	05 Sep 2020 14:40:29
User entered 'No (N)'	System	05 Sep 2020 14:40:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-05T09:41:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ef732fd8-719e-467b-8b82-0133751ef6e0'	System	05 Sep 2020 14:40:29
User entered '05 Sep 2020 09:41'	System	05 Sep 2020 14:40:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 16:43'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 2'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:48:52', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a623f2a3-cc02-4b7c-8579-ec8103bc6bee'	System	06 Sep 2020 13:49:01
User entered 'None (0)'	System	06 Sep 2020 13:49:01

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:49:02', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a623f2a3-cc02-4b7c-8579-ec8103bc6bee'	System	06 Sep 2020 13:49:01
User entered 'None (0)'	System	06 Sep 2020 13:49:01

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:49:24', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a623f2a3-cc02-4b7c-8579-ec8103bc6bee'	System	06 Sep 2020 13:49:01
User entered 'Some interference with activity (2)'	System	06 Sep 2020 13:49:01

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:49:51', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a623f2a3-cc02-4b7c-8579-ec8103bc6bee'	System	06 Sep 2020 13:49:01
User entered 'Some interference with activity (2)'	System	06 Sep 2020 13:49:01

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:49:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a623f2a3-cc02-4b7c-8579-ec8103bc6bee'	System	06 Sep 2020 13:49:01
User entered 'None (0)'	System	06 Sep 2020 13:49:01

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:49:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a623f2a3-cc02-4b7c-8579-ec8103bc6bee'	System	06 Sep 2020 13:49:01
User entered 'None (0)'	System	06 Sep 2020 13:49:01

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-06T08:50:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a623f2a3-cc02-4b7c-8579-ec8103bc6bee'	System	06 Sep 2020 13:49:01
User entered 'No (N)'	System	06 Sep 2020 13:49:01

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-06T08:50:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a623f2a3-cc02-4b7c-8579-ec8103bc6bee'	System	06 Sep 2020 13:49:01
User entered '06 Sep 2020 08:50'	System	06 Sep 2020 13:49:01

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 3'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:45:28', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '23f3ed56-c9f7-4592-b88e-6a5d3ebf7bfc'	System	07 Sep 2020 12:45:12
User entered 'None (0)'	System	07 Sep 2020 12:45:12

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:45:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '23f3ed56-c9f7-4592-b88e-6a5d3ebf7bfc'	System	07 Sep 2020 12:45:12
User entered 'Some interference with activity (2)'	System	07 Sep 2020 12:45:12

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:45:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '23f3ed56-c9f7-4592-b88e-6a5d3ebf7bfc'	System	07 Sep 2020 12:45:12
User entered 'No interference with activity (1)'	System	07 Sep 2020 12:45:12

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:45:59', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '23f3ed56-c9f7-4592-b88e-6a5d3ebf7bfc'	System	07 Sep 2020 12:45:12
User entered 'No interference with activity (1)'	System	07 Sep 2020 12:45:12

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:46:03', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '23f3ed56-c9f7-4592-b88e-6a5d3ebf7bfc'	System	07 Sep 2020 12:45:12
User entered 'None (0)'	System	07 Sep 2020 12:45:12

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:46:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '23f3ed56-c9f7-4592-b88e-6a5d3ebf7bfc'	System	07 Sep 2020 12:45:12
User entered 'None (0)'	System	07 Sep 2020 12:45:12

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-07T07:46:15', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '23f3ed56-c9f7-4592-b88e-6a5d3ebf7bfc'	System	07 Sep 2020 12:45:12
User entered 'No (N)'	System	07 Sep 2020 12:45:12

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-07T07:46:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '23f3ed56-c9f7-4592-b88e-6a5d3ebf7bfc'	System	07 Sep 2020 12:45:12
User entered '07 Sep 2020 07:46'	System	07 Sep 2020 12:45:12

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 4'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:03:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c2a81b01-84d7-45a6-9f27-a5d733c7c1d6'	System	08 Sep 2020 11:03:33
User entered 'None (0)'	System	08 Sep 2020 11:03:33

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:03:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c2a81b01-84d7-45a6-9f27-a5d733c7c1d6'	System	08 Sep 2020 11:03:33
User entered 'None (0)'	System	08 Sep 2020 11:03:33

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:04:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c2a81b01-84d7-45a6-9f27-a5d733c7c1d6'	System	08 Sep 2020 11:03:33
User entered 'Some interference with activity (2)'	System	08 Sep 2020 11:03:33

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:04:26', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c2a81b01-84d7-45a6-9f27-a5d733c7c1d6'	System	08 Sep 2020 11:03:33
User entered 'No interference with activity (1)'	System	08 Sep 2020 11:03:33

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:04:30', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c2a81b01-84d7-45a6-9f27-a5d733c7c1d6'	System	08 Sep 2020 11:03:33
User entered 'None (0)'	System	08 Sep 2020 11:03:33

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:04:34', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c2a81b01-84d7-45a6-9f27-a5d733c7c1d6'	System	08 Sep 2020 11:03:33
User entered 'None (0)'	System	08 Sep 2020 11:03:33

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-08T06:04:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c2a81b01-84d7-45a6-9f27-a5d733c7c1d6'	System	08 Sep 2020 11:03:33
User entered 'No (N)'	System	08 Sep 2020 11:03:33

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-08T06:04:43', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c2a81b01-84d7-45a6-9f27-a5d733c7c1d6'	System	08 Sep 2020 11:03:33
User entered '08 Sep 2020 06:04'	System	08 Sep 2020 11:03:33

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 5'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:50:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9678ab79-ee00-47b3-b630-22ddcda4afb4'	System	09 Sep 2020 10:50:29
User entered 'None (0)'	System	09 Sep 2020 10:50:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:51:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9678ab79-ee00-47b3-b630-22ddcda4afb4'	System	09 Sep 2020 10:50:29
User entered 'None (0)'	System	09 Sep 2020 10:50:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:51:11', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9678ab79-ee00-47b3-b630-22ddcda4afb4'	System	09 Sep 2020 10:50:29
User entered 'No interference with activity (1)'	System	09 Sep 2020 10:50:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:51:18', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9678ab79-ee00-47b3-b630-22ddcda4afb4'	System	09 Sep 2020 10:50:29
User entered 'No interference with activity (1)'	System	09 Sep 2020 10:50:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:51:21', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9678ab79-ee00-47b3-b630-22ddcda4afb4'	System	09 Sep 2020 10:50:29
User entered 'None (0)'	System	09 Sep 2020 10:50:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:51:25', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9678ab79-ee00-47b3-b630-22ddcda4afb4'	System	09 Sep 2020 10:50:29
User entered 'None (0)'	System	09 Sep 2020 10:50:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-09T05:51:29', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9678ab79-ee00-47b3-b630-22ddcda4afb4'	System	09 Sep 2020 10:50:29
User entered 'No (N)'	System	09 Sep 2020 10:50:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-09T05:51:39', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9678ab79-ee00-47b3-b630-22ddcda4afb4'	System	09 Sep 2020 10:50:29
User entered '09 Sep 2020 05:51'	System	09 Sep 2020 10:50:29

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 6'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:47:41', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3c1ba70f-7df1-485a-8b02-4f433cf8b85f'	System	10 Sep 2020 10:47:18
User entered 'None (0)'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:47:46', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3c1ba70f-7df1-485a-8b02-4f433cf8b85f'	System	10 Sep 2020 10:47:18
User entered 'None (0)'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:47:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3c1ba70f-7df1-485a-8b02-4f433cf8b85f'	System	10 Sep 2020 10:47:18
User entered 'No interference with activity (1)'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:48:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3c1ba70f-7df1-485a-8b02-4f433cf8b85f'	System	10 Sep 2020 10:47:18
User entered 'No interference with activity (1)'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:48:15', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3c1ba70f-7df1-485a-8b02-4f433cf8b85f'	System	10 Sep 2020 10:47:18
User entered 'None (0)'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:48:18', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3c1ba70f-7df1-485a-8b02-4f433cf8b85f'	System	10 Sep 2020 10:47:18
User entered 'None (0)'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-10T05:48:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3c1ba70f-7df1-485a-8b02-4f433cf8b85f'	System	10 Sep 2020 10:47:18
User entered 'No (N)'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-10T05:48:28', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3c1ba70f-7df1-485a-8b02-4f433cf8b85f' User entered '10 Sep 2020 05:48'	System	10 Sep 2020 10:47:18
	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 7'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:22:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8922b538-df48-4377-ba8e-64332d27f15d'	System	11 Sep 2020 11:22:11
User entered 'None (0)'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:22:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8922b538-df48-4377-ba8e-64332d27f15d'	System	11 Sep 2020 11:22:11
User entered 'None (0)'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:22:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8922b538-df48-4377-ba8e-64332d27f15d'	System	11 Sep 2020 11:22:11
User entered 'No interference with activity (1)'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:23:03', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8922b538-df48-4377-ba8e-64332d27f15d'	System	11 Sep 2020 11:22:11
User entered 'No interference with activity (1)'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:23:07', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8922b538-df48-4377-ba8e-64332d27f15d'	System	11 Sep 2020 11:22:11
User entered 'None (0)'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:23:11', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8922b538-df48-4377-ba8e-64332d27f15d'	System	11 Sep 2020 11:22:11
User entered 'None (0)'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-11T06:23:18', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8922b538-df48-4377-ba8e-64332d27f15d'	System	11 Sep 2020 11:22:11
User entered 'No (N)'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-11T06:23:22', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8922b538-df48-4377-ba8e-64332d27f15d'	System	11 Sep 2020 11:22:11
User entered '11 Sep 2020 06:23'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 10:47:18
User entered 'Day 8'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-12T08:26:44', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b66967d6-ee1e-410e-badf-75c441dfe406'	System	12 Sep 2020 13:25:38
User entered 'No interference with activity (1)'	System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-12T08:26:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b66967d6-ee1e-410e-badf-75c441dfe406'	System	12 Sep 2020 13:25:38
User entered '12 Sep 2020 08:26'	System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 11:22:11
User entered 'Day 9'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-13T05:40:22', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c50f8771-e58e-4ee0-83f1-b983c6ffe926'	System	13 Sep 2020 10:39:15
User entered 'No interference with activity (1)'	System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-13T05:40:28', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c50f8771-e58e-4ee0-83f1-b983c6ffe926'	System	13 Sep 2020 10:39:15
User entered '13 Sep 2020 05:40'	System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 13:25:38
User entered 'Day 10'	System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-14T07:13:40', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '437c5d92-bd4b-492c-9b36-6568763e73af'	System	14 Sep 2020 12:12:32
User entered 'No interference with activity (1)'	System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-14T07:13:44', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '437c5d92-bd4b-492c-9b36-6568763e73af'	System	14 Sep 2020 12:12:32
User entered '14 Sep 2020 07:13'	System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Sep 2020 10:39:15
User entered 'Day 11'	System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-15T06:25:40', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f2910e79-cad6-422c-a6c7-e6bc60f683e9'	System	15 Sep 2020 11:24:32
User entered 'No interference with activity (1)'	System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-15T06:25:46', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f2910e79-cad6-422c-a6c7-e6bc60f683e9'	System	15 Sep 2020 11:24:32
User entered '15 Sep 2020 06:25'	System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 12:12:32
User entered 'Day 12'	System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-16T06:00:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '856c02d0-4be5-4c50-a0fb-7b5488059d70'	System	16 Sep 2020 10:59:38
User entered 'No interference with activity (1)'	System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-16T06:00:53', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '856c02d0-4be5-4c50-a0fb-7b5488059d70'	System	16 Sep 2020 10:59:38
User entered '16 Sep 2020 06:00'	System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 11:24:32
User entered 'Day 13'	System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-17T09:37:26', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '206f02e7-38a4-440f-8052-4b402231dbcd'	System	17 Sep 2020 14:36:31
User entered 'No interference with activity (1)'	System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-17T09:37:29', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '206f02e7-38a4-440f-8052-4b402231dbcd'	System	17 Sep 2020 14:36:31
User entered '17 Sep 2020 09:37'	System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 10:59:38
User entered 'Day 14'	System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-18T08:17:39', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9c9fe773-49a3-4536-b263-a5023bcbb322'	System	18 Sep 2020 13:16:30
User entered 'No interference with activity (1)'	System	18 Sep 2020 13:16:30

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-18T08:17:43', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9c9fe773-49a3-4536-b263-a5023bcbb322'	System	18 Sep 2020 13:16:30
User entered '18 Sep 2020 08:17'	System	18 Sep 2020 13:16:30

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 14:36:31
User entered 'Day 15'	System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-19T07:19:18', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c7ed5f53-da38-48f4-b79e-a40311035de7'	System	19 Sep 2020 12:18:05
User entered 'No interference with activity (1)'	System	19 Sep 2020 12:18:05

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-19T07:19:21', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c7ed5f53-da38-48f4-b79e-a40311035de7'	System	19 Sep 2020 12:18:05
User entered '19 Sep 2020 07:19'	System	19 Sep 2020 12:18:05

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 13:16:30
User entered 'Day 16'	System	18 Sep 2020 13:16:30

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-20T09:17:22', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8c89e0fb-d856-4e83-9273-2d97e42f11c3'	System	20 Sep 2020 14:16:15
User entered 'No interference with activity (1)'	System	20 Sep 2020 14:16:15

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-20T09:17:31', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8c89e0fb-d856-4e83-9273-2d97e42f11c3'	System	20 Sep 2020 14:16:15
User entered '20 Sep 2020 09:17'	System	20 Sep 2020 14:16:15

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 13:16:30

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 13:16:30

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 12:18:05
User entered 'Day 17'	System	19 Sep 2020 12:18:05

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-21T06:00:05', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f67c824a-3668-4e91-aaeb-065287b4de32'	System	21 Sep 2020 10:58:54
User entered 'None (0)'	System	21 Sep 2020 10:58:54

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-21T06:00:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f67c824a-3668-4e91-aaeb-065287b4de32'	System	21 Sep 2020 10:58:54
User entered '21 Sep 2020 06:00'	System	21 Sep 2020 10:58:54

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 12:18:05

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 12:18:05

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 10:47:18
User entered 'Day 8'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-12T08:26:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '7753635b-8e06-43d6-a44a-d598b01cf262'	System	12 Sep 2020 13:25:55
User entered 'No interference with activity (1)'	System	12 Sep 2020 13:25:55

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-12T08:27:05', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '7753635b-8e06-43d6-a44a-d598b01cf262'	System	12 Sep 2020 13:25:55
User entered '12 Sep 2020 08:27'	System	12 Sep 2020 13:25:55

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 11:22:11
User entered 'Day 9'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-13T05:40:59', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5b013914-2cb9-4e3a-9a0c-1eded2a33016'	System	13 Sep 2020 10:39:50
User entered 'No interference with activity (1)'	System	13 Sep 2020 10:39:50

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-13T05:41:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5b013914-2cb9-4e3a-9a0c-1eded2a33016'	System	13 Sep 2020 10:39:50
User entered '13 Sep 2020 05:41'	System	13 Sep 2020 10:39:50

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 13:25:55
User entered 'Day 10'	System	12 Sep 2020 13:25:55

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-14T07:13:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '2f125d57-92c9-4068-92ff-55d06ec8e2ce'	System	14 Sep 2020 12:12:38
User entered 'No interference with activity (1)'	System	14 Sep 2020 12:12:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-14T07:13:52', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '2f125d57-92c9-4068-92ff-55d06ec8e2ce'	System	14 Sep 2020 12:12:38
User entered '14 Sep 2020 07:13'	System	14 Sep 2020 12:12:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 13:25:55

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 13:25:55

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Sep 2020 10:39:50
User entered 'Day 11'	System	13 Sep 2020 10:39:50

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-15T06:25:52', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '79a38a5b-0437-4384-a91e-c213197cfbe2'	System	15 Sep 2020 11:24:43
User entered 'No interference with activity (1)'	System	15 Sep 2020 11:24:43

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-15T06:25:57', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '79a38a5b-0437-4384-a91e-c213197cfbe2'	System	15 Sep 2020 11:24:43
User entered '15 Sep 2020 06:25'	System	15 Sep 2020 11:24:43

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 10:39:50

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 10:39:50

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 12:12:38
User entered 'Day 12'	System	14 Sep 2020 12:12:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-16T06:01:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'e805dce4-e589-4279-93f5-962fc25acd84'	System	16 Sep 2020 10:59:45
User entered 'No interference with activity (1)'	System	16 Sep 2020 10:59:45

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-16T06:01:03', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'e805dce4-e589-4279-93f5-962fc25acd84'	System	16 Sep 2020 10:59:45
User entered '16 Sep 2020 06:01'	System	16 Sep 2020 10:59:45

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 12:12:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 12:12:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 11:24:43
User entered 'Day 13'	System	15 Sep 2020 11:24:43

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-17T09:37:33', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'fb6d1096-8a40-43d1-9f1b-81f0bceb27d1'	System	17 Sep 2020 14:37:01
User entered 'No interference with activity (1)'	System	17 Sep 2020 14:37:01

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-17T09:37:36', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'fb6d1096-8a40-43d1-9f1b-81f0bceb27d1'	System	17 Sep 2020 14:37:01
User entered '17 Sep 2020 09:37'	System	17 Sep 2020 14:37:01

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 11:24:43

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 11:24:43

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 10:59:45
User entered 'Day 14'	System	16 Sep 2020 10:59:45

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-18T08:17:47', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '7dae146e-1cef-4416-8df5-5696bfdb448f'	System	18 Sep 2020 13:16:38
User entered 'No interference with activity (1)'	System	18 Sep 2020 13:16:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-18T08:17:53', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '7dae146e-1cef-4416-8df5-5696bfbdb448f' User entered '18 Sep 2020 08:17'	System	18 Sep 2020 13:16:38
	System	18 Sep 2020 13:16:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 10:59:45

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 10:59:45

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 14:37:01
User entered 'Day 15'	System	17 Sep 2020 14:37:01

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-19T07:19:26', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f242b6f6-72da-460b-b293-8328d2615c88'	System	19 Sep 2020 12:18:12
User entered 'No interference with activity (1)'	System	19 Sep 2020 12:18:12

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-19T07:19:29', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f242b6f6-72da-460b-b293-8328d2615c88'	System	19 Sep 2020 12:18:12
User entered '19 Sep 2020 07:19'	System	19 Sep 2020 12:18:12

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:37:01

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:37:01

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 13:16:38
User entered 'Day 16'	System	18 Sep 2020 13:16:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-20T09:17:48', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9cabba56-8ce3-497d-b6a5-3bec80327369'	System	20 Sep 2020 14:16:34
User entered 'None (0)'	System	20 Sep 2020 14:16:34

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-20T09:17:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9cabba56-8ce3-497d-b6a5-3bec80327369'	System	20 Sep 2020 14:16:34
User entered '20 Sep 2020 09:17'	System	20 Sep 2020 14:16:34

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 13:16:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 13:16:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 10:47:18
User entered 'Day 8'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-12T08:27:10', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a8e7f8fd-b405-48bb-9e80-71f2543be60d'	System	12 Sep 2020 13:26:05
User entered 'No (N)'	System	12 Sep 2020 13:26:05

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-12T08:27:17', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a8e7f8fd-b405-48bb-9e80-71f2543be60d'	System	12 Sep 2020 13:26:05
User entered '12 Sep 2020 08:27'	System	12 Sep 2020 13:26:05

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 11:22:11
User entered 'Day 9'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-13T05:41:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '7f713853-9e9c-41d8-ab5a-a129e85c4243'	System	13 Sep 2020 10:40:02
User entered 'No (N)'	System	13 Sep 2020 10:40:02

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-13T05:41:15', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '7f713853-9e9c-41d8-ab5a-a129e85c4243'	System	13 Sep 2020 10:40:02
User entered '13 Sep 2020 05:41'	System	13 Sep 2020 10:40:02

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 13:25:38
User entered 'Day 10'	System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-14T07:13:57', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1eae2a6b-1514-441a-8353-42ad6902f22c'	System	14 Sep 2020 12:12:46
User entered 'No (N)'	System	14 Sep 2020 12:12:46

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-14T07:14:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1eae2a6b-1514-441a-8353-42ad6902f22c'	System	14 Sep 2020 12:12:46
User entered '14 Sep 2020 07:14'	System	14 Sep 2020 12:12:46

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Sep 2020 10:39:15
User entered 'Day 11'	System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-15T06:26:03', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '38e4ab43-ca67-4efe-b2a9-c22696601866'	System	15 Sep 2020 11:24:53
User entered 'No (N)'	System	15 Sep 2020 11:24:53

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-15T06:26:08', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '38e4ab43-ca67-4efe-b2a9-c22696601866'	System	15 Sep 2020 11:24:53
User entered '15 Sep 2020 06:26'	System	15 Sep 2020 11:24:53

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 12:12:32
User entered 'Day 12'	System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-16T06:01:06', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '363e09cf-6227-46c7-b800-3cf46d77e35c'	System	16 Sep 2020 10:59:53
User entered 'No (N)'	System	16 Sep 2020 10:59:53

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-16T06:01:08', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '363e09cf-6227-46c7-b800-3cf46d77e35c'	System	16 Sep 2020 10:59:53
User entered '16 Sep 2020 06:01'	System	16 Sep 2020 10:59:53

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 11:24:32
User entered 'Day 13'	System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-17T09:37:41', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'dda4ef25-e3e8-45e4-9654-6dd7dce2280d'	System	17 Sep 2020 14:36:56
User entered 'No (N)'	System	17 Sep 2020 14:36:56

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-17T09:37:43', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'dda4ef25-e3e8-45e4-9654-6dd7dce2280d'	System	17 Sep 2020 14:36:56
User entered '17 Sep 2020 09:37'	System	17 Sep 2020 14:36:56

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 10:59:38
User entered 'Day 14'	System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-18T08:17:57', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c532e5a5-3b4a-4ba2-bbbe-57ce19cdcf17'	System	18 Sep 2020 13:16:44
User entered 'No (N)'	System	18 Sep 2020 13:16:44

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-18T08:17:59', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c532e5a5-3b4a-4ba2-bbbe-57ce19cdcf17'	System	18 Sep 2020 13:16:44
User entered '18 Sep 2020 08:17'	System	18 Sep 2020 13:16:44

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 14:36:31
User entered 'Day 15'	System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-19T07:19:34', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '64a27369-17a9-44da-909a-2dfac5e82c3c'	System	19 Sep 2020 12:18:18
User entered 'No (N)'	System	19 Sep 2020 12:18:18

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-19T07:19:35', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '64a27369-17a9-44da-909a-2dfac5e82c3c'	System	19 Sep 2020 12:18:18
User entered '19 Sep 2020 07:19'	System	19 Sep 2020 12:18:18

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 13:16:30
User entered 'Day 16'	System	18 Sep 2020 13:16:30

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-09-20T09:17:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '17b7a388-b85d-437b-a2a6-1fc4412d53af'	System	20 Sep 2020 14:16:40
User entered 'No (N)'	System	20 Sep 2020 14:16:40

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-09-20T09:17:57', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '17b7a388-b85d-437b-a2a6-1fc4412d53af'	System	20 Sep 2020 14:16:40
User entered '20 Sep 2020 09:17'	System	20 Sep 2020 14:16:40

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 13:16:30

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 13:16:30

US3492064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	11 Sep 2020 16:52:37

US3492064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Elena Llinas (b) (4) (b) (4)	11 Sep 2020 16:52:37

US3492064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4) (b) (4)	11 Sep 2020 16:52:37

US3492064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elena Llinas (b) (4) (b) (4)	11 Sep 2020 16:52:37

US3492064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	11 Sep 2020 16:52:41

US3492064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 16:52:41

US3492064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 19:56:28

US3492064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 19:56:28

US3492064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 19:56:28

US3492064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 19:56:28

US3492064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 19:56:34

US3492064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:56:34

US3492064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 20:15:45

US3492064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 20:15:45

US3492064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 20:15:45

US3492064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 20:15:45

US3492064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 20:15:49

US3492064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 20:15:49

US3492064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 16:30:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 16:30:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Oct 2020 16:30:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	02 Oct 2020 16:30:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 18:25:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 18:25:01
User entered '10:34' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 18:25:01
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 18:23:57
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 10:34'	System	02 Oct 2020 18:25:01
User entered empty.	System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.1' F	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'not specified'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '131'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '12:50'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:50'	System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'not specified'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '65'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '67'	(b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:24:31

US3492064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 18:24:31

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '12:20'	(b) (4), (b) (6)	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 12:20'	System	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:24:11

US3492064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 18:24:11

US3492064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:50'	(b) (4), (b) (6)	02 Oct 2020 18:24:11

US3492064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 10:50'	System	02 Oct 2020 18:24:11

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:29

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:00'	(b) (4), (b) (6)	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:00'	System	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:29

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 17:54:06

US3492064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 17:54:06

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:56:44', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a68f6c17-f2e6-4f21-af53-21bbfb44af7f'	System	02 Oct 2020 17:55:37
User entered 'Yes (Y)'	System	02 Oct 2020 17:55:37

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:56:51', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a68f6c17-f2e6-4f21-af53-21bbfb44af7f'	System	02 Oct 2020 17:55:37
User entered '97.5'	System	02 Oct 2020 17:55:37

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:56:57', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a68f6c17-f2e6-4f21-af53-21bbfb44af7f'	System	02 Oct 2020 17:55:37
User entered 'No (N)'	System	02 Oct 2020 17:55:37

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:57:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a68f6c17-f2e6-4f21-af53-21bbfb44af7f'	System	02 Oct 2020 17:55:37
User entered '02 Oct 2020 12:57'	System	02 Oct 2020 17:55:37

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:40'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 15:10'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 16:05'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 2'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:30:44', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '4d4c7863-b811-4c5a-a0c0-b8432fbfb04a'	System	03 Oct 2020 19:29:42
User entered 'Yes (Y)'	System	03 Oct 2020 19:29:42

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:30:57', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '4d4c7863-b811-4c5a-a0c0-b8432fbfb04a'	System	03 Oct 2020 19:29:42
User entered '97.1'	System	03 Oct 2020 19:29:42

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:31:02', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '4d4c7863-b811-4c5a-a0c0-b8432fbfb04a'	System	03 Oct 2020 19:29:42
User entered 'No (N)'	System	03 Oct 2020 19:29:42

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:31:10', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '4d4c7863-b811-4c5a-a0c0-b8432fbfb04a'	System	03 Oct 2020 19:29:42
User entered '03 Oct 2020 14:31'	System	03 Oct 2020 19:29:42

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 3'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:20:45', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '669d4e22-2043-4777-873d-996b47bb113a'	System	04 Oct 2020 17:21:21
User entered 'Yes (Y)'	System	04 Oct 2020 17:21:21

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:22:43', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '669d4e22-2043-4777-873d-996b47bb113a'	System	04 Oct 2020 17:21:21
User entered '96.6'	System	04 Oct 2020 17:21:21

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:20:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '669d4e22-2043-4777-873d-996b47bb113a'	System	04 Oct 2020 17:21:21
User entered 'No (N)'	System	04 Oct 2020 17:21:21

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:22:51', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '669d4e22-2043-4777-873d-996b47bb113a'	System	04 Oct 2020 17:21:21
User entered '04 Oct 2020 12:22'	System	04 Oct 2020 17:21:21

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 4'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T12:12:19', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f42941cf-f590-4646-9bff-c326e63dd53f'	System	05 Oct 2020 18:10:58
User entered 'Yes (Y)'	System	05 Oct 2020 18:10:58

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T12:12:45', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f42941cf-f590-4646-9bff-c326e63dd53f'	System	05 Oct 2020 18:10:58
User entered '97.8'	System	05 Oct 2020 18:10:58

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:12:19', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f42941cf-f590-4646-9bff-c326e63dd53f'	System	05 Oct 2020 18:10:58
User entered 'No (N)'	System	05 Oct 2020 18:10:58

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:12:26', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f42941cf-f590-4646-9bff-c326e63dd53f'	System	05 Oct 2020 18:10:58
User entered '05 Oct 2020 13:12'	System	05 Oct 2020 18:10:58

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 5'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:32:53', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b95dcd1e-0ff2-48b3-83c8-7c88abceb077'	System	06 Oct 2020 22:31:38
User entered 'Yes (Y)'	System	06 Oct 2020 22:31:38

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b95dcd1e-0ff2-48b3-83c8-7c88abceb077'	System	06 Oct 2020 22:31:38
User entered '97.9'	System	06 Oct 2020 22:31:38

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:03', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b95dcd1e-0ff2-48b3-83c8-7c88abceb077'	System	06 Oct 2020 22:31:38
User entered 'No (N)'	System	06 Oct 2020 22:31:38

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:08', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b95dcd1e-0ff2-48b3-83c8-7c88abceb077'	System	06 Oct 2020 22:31:38
User entered '06 Oct 2020 17:33'	System	06 Oct 2020 22:31:38

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 6'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:08:54', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3ffbaa89-1ed1-4615-bb45-db387266209b'	System	07 Oct 2020 19:08:04
User entered 'Yes (Y)'	System	07 Oct 2020 19:08:04

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:09:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3ffbaa89-1ed1-4615-bb45-db387266209b'	System	07 Oct 2020 19:08:04
User entered '98.2'	System	07 Oct 2020 19:08:04

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:09:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3ffbaa89-1ed1-4615-bb45-db387266209b'	System	07 Oct 2020 19:08:04
User entered 'No (N)'	System	07 Oct 2020 19:08:04

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:09:34', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3ffbaa89-1ed1-4615-bb45-db387266209b'	System	07 Oct 2020 19:08:04
User entered '07 Oct 2020 14:09'	System	07 Oct 2020 19:08:04

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 7'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:15:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e507ea5-dc25-436d-a6ac-36c1793d4ab7'	System	08 Oct 2020 21:13:45
User entered 'Yes (Y)'	System	08 Oct 2020 21:13:45

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:15:10', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e507ea5-dc25-436d-a6ac-36c1793d4ab7'	System	08 Oct 2020 21:13:45
User entered '97.9'	System	08 Oct 2020 21:13:45

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:15:13', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e507ea5-dc25-436d-a6ac-36c1793d4ab7'	System	08 Oct 2020 21:13:45
User entered 'No (N)'	System	08 Oct 2020 21:13:45

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:15:21', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e507ea5-dc25-436d-a6ac-36c1793d4ab7'	System	08 Oct 2020 21:13:45
User entered '08 Oct 2020 16:15'	System	08 Oct 2020 21:13:45

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-02T12:57:20', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8bab5da8-3d84-446a-9348-7c7800897e06'	System	02 Oct 2020 17:56:26
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 17:56:26

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:57:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8bab5da8-3d84-446a-9348-7c7800897e06'	System	02 Oct 2020 17:56:26
User entered 'No (N)'	System	02 Oct 2020 17:56:26

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:57:39', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8bab5da8-3d84-446a-9348-7c7800897e06'	System	02 Oct 2020 17:56:26
User entered 'No (N)'	System	02 Oct 2020 17:56:26

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-02T12:57:46', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8bab5da8-3d84-446a-9348-7c7800897e06'	System	02 Oct 2020 17:56:26
User entered 'None (1)'	System	02 Oct 2020 17:56:26

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:57:54', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8bab5da8-3d84-446a-9348-7c7800897e06'	System	02 Oct 2020 17:56:26
User entered '02 Oct 2020 12:57'	System	02 Oct 2020 17:56:26

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:40'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 15:10'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 16:05'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 2'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-03T14:31:24', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '16febd1c-30de-4d82-9948-097cea8c4dc0'	System	03 Oct 2020 19:30:19
User entered 'None (1)'	System	03 Oct 2020 19:30:19

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:31:29', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '16febd1c-30de-4d82-9948-097cea8c4dc0'	System	03 Oct 2020 19:30:19
User entered 'No (N)'	System	03 Oct 2020 19:30:19

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:31:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '16febd1c-30de-4d82-9948-097cea8c4dc0'	System	03 Oct 2020 19:30:19
User entered 'No (N)'	System	03 Oct 2020 19:30:19

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-03T14:31:40', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '16febd1c-30de-4d82-9948-097cea8c4dc0'	System	03 Oct 2020 19:30:19
User entered 'None (1)'	System	03 Oct 2020 19:30:19

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:31:48', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '16febd1c-30de-4d82-9948-097cea8c4dc0'	System	03 Oct 2020 19:30:19
User entered '03 Oct 2020 14:31'	System	03 Oct 2020 19:30:19

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 3'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-04T12:23:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cc6607c2-ae15-432d-b417-3eb4cf2f0d66'	System	04 Oct 2020 17:22:26
User entered 'None (1)'	System	04 Oct 2020 17:22:26

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:23:33', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cc6607c2-ae15-432d-b417-3eb4cf2f0d66'	System	04 Oct 2020 17:22:26
User entered 'No (N)'	System	04 Oct 2020 17:22:26

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:23:37', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cc6607c2-ae15-432d-b417-3eb4cf2f0d66'	System	04 Oct 2020 17:22:26
User entered 'No (N)'	System	04 Oct 2020 17:22:26

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-04T12:23:48', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cc6607c2-ae15-432d-b417-3eb4cf2f0d66'	System	04 Oct 2020 17:22:26
User entered 'None (1)'	System	04 Oct 2020 17:22:26

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:23:56', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cc6607c2-ae15-432d-b417-3eb4cf2f0d66'	System	04 Oct 2020 17:22:26
User entered '04 Oct 2020 12:23'	System	04 Oct 2020 17:22:26

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 4'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-05T13:12:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b4742dd9-af10-457e-932c-74a8d340fbdb'	System	05 Oct 2020 18:11:38
User entered 'None (1)'	System	05 Oct 2020 18:11:38

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:12:42', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b4742dd9-af10-457e-932c-74a8d340fbdb'	System	05 Oct 2020 18:11:38
User entered 'No (N)'	System	05 Oct 2020 18:11:38

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:12:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b4742dd9-af10-457e-932c-74a8d340fbdb'	System	05 Oct 2020 18:11:38
User entered 'No (N)'	System	05 Oct 2020 18:11:38

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-05T13:12:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b4742dd9-af10-457e-932c-74a8d340fbdb'	System	05 Oct 2020 18:11:38
User entered 'None (1)'	System	05 Oct 2020 18:11:38

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:13:07', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b4742dd9-af10-457e-932c-74a8d340fbdb'	System	05 Oct 2020 18:11:38
User entered '05 Oct 2020 13:13'	System	05 Oct 2020 18:11:38

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 5'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:17', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '99335079-4d80-4b97-870a-b2bf9ef0028f'	System	06 Oct 2020 22:32:09
User entered 'None (1)'	System	06 Oct 2020 22:32:09

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:21', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '99335079-4d80-4b97-870a-b2bf9ef0028f'	System	06 Oct 2020 22:32:09
User entered 'No (N)'	System	06 Oct 2020 22:32:09

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:25', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '99335079-4d80-4b97-870a-b2bf9ef0028f'	System	06 Oct 2020 22:32:09
User entered 'No (N)'	System	06 Oct 2020 22:32:09

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '99335079-4d80-4b97-870a-b2bf9ef0028f'	System	06 Oct 2020 22:32:09
User entered 'None (1)'	System	06 Oct 2020 22:32:09

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:40', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '99335079-4d80-4b97-870a-b2bf9ef0028f' User entered '06 Oct 2020 17:33'	System	06 Oct 2020 22:32:09
	System	06 Oct 2020 22:32:09

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 6'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-07T14:10:28', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '28d3d291-5971-4d04-89e8-b4dde13cfddb'	System	07 Oct 2020 19:09:44
User entered 'None (1)'	System	07 Oct 2020 19:09:44

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:10:33', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '28d3d291-5971-4d04-89e8-b4dde13cfddb'	System	07 Oct 2020 19:09:44
User entered 'No (N)'	System	07 Oct 2020 19:09:44

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:10:44', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '28d3d291-5971-4d04-89e8-b4dde13cfddb'	System	07 Oct 2020 19:09:44
User entered 'No (N)'	System	07 Oct 2020 19:09:44

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-07T14:10:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '28d3d291-5971-4d04-89e8-b4dde13cfddb'	System	07 Oct 2020 19:09:44
User entered 'None (1)'	System	07 Oct 2020 19:09:44

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:11:13', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '28d3d291-5971-4d04-89e8-b4dde13cfddb'	System	07 Oct 2020 19:09:44
User entered '07 Oct 2020 14:11'	System	07 Oct 2020 19:09:44

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 7'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-08T16:16:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '53d5ff9f-da01-468c-a081-f4e24cbf1f06'	System	08 Oct 2020 21:15:29
User entered 'None (1)'	System	08 Oct 2020 21:15:29

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:16:42', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '53d5ff9f-da01-468c-a081-f4e24cbf1f06'	System	08 Oct 2020 21:15:29
User entered 'No (N)'	System	08 Oct 2020 21:15:29

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:16:52', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '53d5ff9f-da01-468c-a081-f4e24cbf1f06'	System	08 Oct 2020 21:15:29
User entered 'No (N)'	System	08 Oct 2020 21:15:29

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-08T16:16:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '53d5ff9f-da01-468c-a081-f4e24cbf1f06'	System	08 Oct 2020 21:15:29
User entered 'None (1)'	System	08 Oct 2020 21:15:29

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:17:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '53d5ff9f-da01-468c-a081-f4e24cbf1f06'	System	08 Oct 2020 21:15:29
User entered '08 Oct 2020 16:17'	System	08 Oct 2020 21:15:29

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:58:08', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd4906760-51ca-4473-9b58-6577cb93a858'	System	02 Oct 2020 17:57:41
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:57:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:58:16', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd4906760-51ca-4473-9b58-6577cb93a858'	System	02 Oct 2020 17:57:41
User entered 'None (0)'	System	02 Oct 2020 17:57:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:58:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd4906760-51ca-4473-9b58-6577cb93a858'	System	02 Oct 2020 17:57:41
User entered 'None (0)'	System	02 Oct 2020 17:57:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:58:52', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd4906760-51ca-4473-9b58-6577cb93a858'	System	02 Oct 2020 17:57:41
User entered 'None (0)'	System	02 Oct 2020 17:57:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:58:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd4906760-51ca-4473-9b58-6577cb93a858'	System	02 Oct 2020 17:57:41
User entered 'None (0)'	System	02 Oct 2020 17:57:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:59:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd4906760-51ca-4473-9b58-6577cb93a858'	System	02 Oct 2020 17:57:41
User entered 'None (0)'	System	02 Oct 2020 17:57:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-02T12:59:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd4906760-51ca-4473-9b58-6577cb93a858'	System	02 Oct 2020 17:57:41
User entered 'No (N)'	System	02 Oct 2020 17:57:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-02T12:59:08', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd4906760-51ca-4473-9b58-6577cb93a858'	System	02 Oct 2020 17:57:41
User entered '02 Oct 2020 12:59'	System	02 Oct 2020 17:57:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:40'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 15:10'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 16:05'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 2'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:31:54', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '83c24a88-47af-4ea8-b851-de7e3201e597'	System	03 Oct 2020 19:30:59
User entered 'None (0)'	System	03 Oct 2020 19:30:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:31:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '83c24a88-47af-4ea8-b851-de7e3201e597'	System	03 Oct 2020 19:30:59
User entered 'None (0)'	System	03 Oct 2020 19:30:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:32:05', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '83c24a88-47af-4ea8-b851-de7e3201e597'	System	03 Oct 2020 19:30:59
User entered 'No interference with activity (1)'	System	03 Oct 2020 19:30:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:32:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '83c24a88-47af-4ea8-b851-de7e3201e597'	System	03 Oct 2020 19:30:59
User entered 'No interference with activity (1)'	System	03 Oct 2020 19:30:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:32:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '83c24a88-47af-4ea8-b851-de7e3201e597'	System	03 Oct 2020 19:30:59
User entered 'None (0)'	System	03 Oct 2020 19:30:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:32:17', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '83c24a88-47af-4ea8-b851-de7e3201e597'	System	03 Oct 2020 19:30:59
User entered 'None (0)'	System	03 Oct 2020 19:30:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-03T14:32:21', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '83c24a88-47af-4ea8-b851-de7e3201e597'	System	03 Oct 2020 19:30:59
User entered 'No (N)'	System	03 Oct 2020 19:30:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-03T14:32:30', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '83c24a88-47af-4ea8-b851-de7e3201e597'	System	03 Oct 2020 19:30:59
User entered '03 Oct 2020 14:32'	System	03 Oct 2020 19:30:59

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 3'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:24:41', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '13af49df-2051-4f82-829a-6ccbf91cfb60'	System	04 Oct 2020 17:24:07
User entered 'No interference with activity (1)'	System	04 Oct 2020 17:24:07

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:24:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '13af49df-2051-4f82-829a-6ccbf91cfb60'	System	04 Oct 2020 17:24:07
User entered 'None (0)'	System	04 Oct 2020 17:24:07

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:25:03', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '13af49df-2051-4f82-829a-6ccbf91cfb60'	System	04 Oct 2020 17:24:07
User entered 'No interference with activity (1)'	System	04 Oct 2020 17:24:07

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:25:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '13af49df-2051-4f82-829a-6ccbf91cfb60'	System	04 Oct 2020 17:24:07
User entered 'No interference with activity (1)'	System	04 Oct 2020 17:24:07

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:25:14', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '13af49df-2051-4f82-829a-6ccbf91cfb60'	System	04 Oct 2020 17:24:07
User entered 'None (0)'	System	04 Oct 2020 17:24:07

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:25:25', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '13af49df-2051-4f82-829a-6ccbf91cfb60'	System	04 Oct 2020 17:24:07
User entered 'None (0)'	System	04 Oct 2020 17:24:07

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-04T12:25:31', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '13af49df-2051-4f82-829a-6ccbf91cfb60'	System	04 Oct 2020 17:24:07
User entered 'No (N)'	System	04 Oct 2020 17:24:07

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-04T12:25:35', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '13af49df-2051-4f82-829a-6ccbf91cfb60'	System	04 Oct 2020 17:24:07
User entered '04 Oct 2020 12:25'	System	04 Oct 2020 17:24:07

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 4'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:13:13', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b735fb68-d624-4d96-b276-7d71833d49a3'	System	05 Oct 2020 18:12:48
User entered 'None (0)'	System	05 Oct 2020 18:12:48

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:13:17', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b735fb68-d624-4d96-b276-7d71833d49a3'	System	05 Oct 2020 18:12:48
User entered 'None (0)'	System	05 Oct 2020 18:12:48

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:13:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b735fb68-d624-4d96-b276-7d71833d49a3'	System	05 Oct 2020 18:12:48
User entered 'No interference with activity (1)'	System	05 Oct 2020 18:12:48

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:13:29', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b735fb68-d624-4d96-b276-7d71833d49a3'	System	05 Oct 2020 18:12:48
User entered 'No interference with activity (1)'	System	05 Oct 2020 18:12:48

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:13:37', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b735fb68-d624-4d96-b276-7d71833d49a3'	System	05 Oct 2020 18:12:48
User entered 'None (0)'	System	05 Oct 2020 18:12:48

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:13:41', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b735fb68-d624-4d96-b276-7d71833d49a3'	System	05 Oct 2020 18:12:48
User entered 'None (0)'	System	05 Oct 2020 18:12:48

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-05T13:13:45', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b735fb68-d624-4d96-b276-7d71833d49a3'	System	05 Oct 2020 18:12:48
User entered 'No (N)'	System	05 Oct 2020 18:12:48

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-05T13:14:17', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b735fb68-d624-4d96-b276-7d71833d49a3'	System	05 Oct 2020 18:12:48
User entered '05 Oct 2020 13:14'	System	05 Oct 2020 18:12:48

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 5'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:46', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9732a572-8b22-4522-9e44-615ef31447af'	System	06 Oct 2020 22:33:31
User entered 'None (0)'	System	06 Oct 2020 22:33:31

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:48', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9732a572-8b22-4522-9e44-615ef31447af'	System	06 Oct 2020 22:33:31
User entered 'None (0)'	System	06 Oct 2020 22:33:31

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:52', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9732a572-8b22-4522-9e44-615ef31447af'	System	06 Oct 2020 22:33:31
User entered 'No interference with activity (1)'	System	06 Oct 2020 22:33:31

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:56', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9732a572-8b22-4522-9e44-615ef31447af'	System	06 Oct 2020 22:33:31
User entered 'No interference with activity (1)'	System	06 Oct 2020 22:33:31

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:33:59', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9732a572-8b22-4522-9e44-615ef31447af'	System	06 Oct 2020 22:33:31
User entered 'None (0)'	System	06 Oct 2020 22:33:31

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:34:01', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9732a572-8b22-4522-9e44-615ef31447af'	System	06 Oct 2020 22:33:31
User entered 'None (0)'	System	06 Oct 2020 22:33:31

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-06T17:34:05', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9732a572-8b22-4522-9e44-615ef31447af'	System	06 Oct 2020 22:33:31
User entered 'No (N)'	System	06 Oct 2020 22:33:31

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-06T17:34:11', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9732a572-8b22-4522-9e44-615ef31447af'	System	06 Oct 2020 22:33:31
User entered '06 Oct 2020 17:34'	System	06 Oct 2020 22:33:31

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 6'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:11:19', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '38ccad15-f47a-47d3-b2a8-97541389cf23'	System	07 Oct 2020 19:10:26
User entered 'None (0)'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:11:22', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '38ccad15-f47a-47d3-b2a8-97541389cf23'	System	07 Oct 2020 19:10:26
User entered 'None (0)'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:11:29', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '38ccad15-f47a-47d3-b2a8-97541389cf23'	System	07 Oct 2020 19:10:26
User entered 'No interference with activity (1)'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:11:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '38ccad15-f47a-47d3-b2a8-97541389cf23'	System	07 Oct 2020 19:10:26
User entered 'No interference with activity (1)'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:11:35', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '38ccad15-f47a-47d3-b2a8-97541389cf23'	System	07 Oct 2020 19:10:26
User entered 'None (0)'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:11:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '38ccad15-f47a-47d3-b2a8-97541389cf23'	System	07 Oct 2020 19:10:26
User entered 'None (0)'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-07T14:11:42', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '38ccad15-f47a-47d3-b2a8-97541389cf23'	System	07 Oct 2020 19:10:26
User entered 'No (N)'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-07T14:11:56', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '38ccad15-f47a-47d3-b2a8-97541389cf23'	System	07 Oct 2020 19:10:26
User entered '07 Oct 2020 14:11'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 17:53:57
User entered 'Day 7'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:17:13', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b07371ef-a8ca-4ca5-823d-9d81fae75cea'	System	08 Oct 2020 21:16:26
User entered 'None (0)'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:17:19', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b07371ef-a8ca-4ca5-823d-9d81fae75cea'	System	08 Oct 2020 21:16:26
User entered 'None (0)'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:17:27', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b07371ef-a8ca-4ca5-823d-9d81fae75cea'	System	08 Oct 2020 21:16:26
User entered 'No interference with activity (1)'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:17:31', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b07371ef-a8ca-4ca5-823d-9d81fae75cea'	System	08 Oct 2020 21:16:26
User entered 'No interference with activity (1)'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:17:35', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b07371ef-a8ca-4ca5-823d-9d81fae75cea'	System	08 Oct 2020 21:16:26
User entered 'None (0)'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:17:42', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b07371ef-a8ca-4ca5-823d-9d81fae75cea'	System	08 Oct 2020 21:16:26
User entered 'None (0)'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-08T16:17:51', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b07371ef-a8ca-4ca5-823d-9d81fae75cea'	System	08 Oct 2020 21:16:26
User entered 'No (N)'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-08T16:18:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b07371ef-a8ca-4ca5-823d-9d81fae75cea'	System	08 Oct 2020 21:16:26
User entered '08 Oct 2020 16:18'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 19:10:26
User entered 'Day 8'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-09T17:26:39', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd552eeec-b127-4333-865a-b26de7f38549'	System	09 Oct 2020 22:25:14
User entered 'No interference with activity (1)'	System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-09T17:26:47', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'd552eeec-b127-4333-865a-b26de7f38549'	System	09 Oct 2020 22:25:14
User entered '09 Oct 2020 17:26'	System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 21:16:26
User entered 'Day 9'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-10T14:04:07', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'aeb725af-7802-4a77-81cc-81abef32b977'	System	10 Oct 2020 19:02:39
User entered 'No interference with activity (1)'	System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-10T14:04:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'aeb725af-7802-4a77-81cc-81abef32b977'	System	10 Oct 2020 19:02:39
User entered '10 Oct 2020 14:04'	System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 22:25:14
User entered 'Day 10'	System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-11T14:23:36', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3efb0764-593d-458a-a851-744776dd86d0'	System	11 Oct 2020 19:22:05
User entered 'No interference with activity (1)'	System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-11T14:23:41', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3efb0764-593d-458a-a851-744776dd86d0'	System	11 Oct 2020 19:22:05
User entered '11 Oct 2020 14:23'	System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 19:02:39
User entered 'Day 11'	System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-12T12:00:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '622d3b25-2bb4-4211-9cc2-5018b5696710'	System	12 Oct 2020 16:58:51
User entered 'No interference with activity (1)'	System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-12T12:00:26', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '622d3b25-2bb4-4211-9cc2-5018b5696710'	System	12 Oct 2020 16:58:51
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 19:22:05
User entered 'Day 12'	System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-13T17:39:01', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a9a80c09-aae0-4e58-83b4-711cd2949946'	System	13 Oct 2020 22:37:27
User entered 'No interference with activity (1)'	System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-13T17:39:05', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a9a80c09-aae0-4e58-83b4-711cd2949946'	System	13 Oct 2020 22:37:27
User entered '13 Oct 2020 17:39'	System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 16:58:51
User entered 'Day 13'	System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-14T13:19:40', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f587ba20-6f8b-4981-a737-b539e9b6642e'	System	14 Oct 2020 18:18:08
User entered 'No interference with activity (1)'	System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-14T13:19:44', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f587ba20-6f8b-4981-a737-b539e9b6642e'	System	14 Oct 2020 18:18:08
User entered '14 Oct 2020 13:19'	System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 22:37:27
User entered 'Day 14'	System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-15T12:00:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ac50876a-492b-4090-9182-9f1045baeb34'	System	15 Oct 2020 16:59:17
User entered 'No interference with activity (1)'	System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-15T12:00:54', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ac50876a-492b-4090-9182-9f1045baeb34'	System	15 Oct 2020 16:59:17
User entered '15 Oct 2020 12:00'	System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:18:08
User entered 'Day 15'	System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-16T12:06:28', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5d6d86ce-6d51-4736-ac95-e9900196b43a'	System	16 Oct 2020 17:04:53
User entered 'No interference with activity (1)'	System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-16T12:06:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5d6d86ce-6d51-4736-ac95-e9900196b43a'	System	16 Oct 2020 17:04:53
User entered '16 Oct 2020 12:06'	System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 16:59:17
User entered 'Day 16'	System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-17T12:37:06', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b51afef6-2fc0-407c-b2b9-3d2def4c4867'	System	17 Oct 2020 17:35:33
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:35:33

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-17T12:37:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b51afef6-2fc0-407c-b2b9-3d2def4c4867'	System	17 Oct 2020 17:35:33
User entered '17 Oct 2020 12:37'	System	17 Oct 2020 17:35:33

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:04:53
User entered 'Day 17'	System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-18T12:01:35', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1cd63c67-d570-4637-b4d0-13c11313adfa'	System	18 Oct 2020 16:59:57
User entered 'None (0)'	System	18 Oct 2020 16:59:57

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-18T12:01:37', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1cd63c67-d570-4637-b4d0-13c11313adfa'	System	18 Oct 2020 16:59:57
User entered '18 Oct 2020 12:01'	System	18 Oct 2020 16:59:57

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 19:10:26
User entered 'Day 8'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-09T17:26:54', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '80a979ba-730f-4664-af40-4e5a2c830a09'	System	09 Oct 2020 22:25:26
User entered 'No interference with activity (1)'	System	09 Oct 2020 22:25:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-09T17:26:59', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '80a979ba-730f-4664-af40-4e5a2c830a09'	System	09 Oct 2020 22:25:26
User entered '09 Oct 2020 17:26'	System	09 Oct 2020 22:25:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 21:16:26
User entered 'Day 9'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-10T14:04:17', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'df37f117-f2c3-4206-91cb-60a34e6f4cc3'	System	10 Oct 2020 19:02:46
User entered 'No interference with activity (1)'	System	10 Oct 2020 19:02:46

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-10T14:04:20', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'df37f117-f2c3-4206-91cb-60a34e6f4cc3'	System	10 Oct 2020 19:02:46
User entered '10 Oct 2020 14:04'	System	10 Oct 2020 19:02:46

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 22:25:26
User entered 'Day 10'	System	09 Oct 2020 22:25:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-11T14:23:45', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '249eac5b-08af-4913-a97d-5deb9d316f35'	System	11 Oct 2020 19:22:12
User entered 'No interference with activity (1)'	System	11 Oct 2020 19:22:12

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-11T14:23:48', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '249eac5b-08af-4913-a97d-5deb9d316f35'	System	11 Oct 2020 19:22:12
User entered '11 Oct 2020 14:23'	System	11 Oct 2020 19:22:12

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 22:25:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 22:25:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 19:02:46
User entered 'Day 11'	System	10 Oct 2020 19:02:46

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-12T12:00:30', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1d7199b7-4082-4992-a2d5-4165e87747e8'	System	12 Oct 2020 16:58:57
User entered 'No interference with activity (1)'	System	12 Oct 2020 16:58:57

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-12T12:00:33', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1d7199b7-4082-4992-a2d5-4165e87747e8'	System	12 Oct 2020 16:58:57
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 16:58:57

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 19:02:46

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 19:02:46

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 19:22:12
User entered 'Day 12'	System	11 Oct 2020 19:22:12

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-13T17:39:10', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '57c2c5d5-2388-4e02-ad8b-7f6d5fd032b7'	System	13 Oct 2020 22:37:41
User entered 'No interference with activity (1)'	System	13 Oct 2020 22:37:41

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-13T17:39:14', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '57c2c5d5-2388-4e02-ad8b-7f6d5fd032b7'	System	13 Oct 2020 22:37:41
User entered '13 Oct 2020 17:39'	System	13 Oct 2020 22:37:41

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 19:22:12

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 19:22:12

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 16:58:57
User entered 'Day 13'	System	12 Oct 2020 16:58:57

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-14T13:19:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '41bd04a6-cb66-4baf-a311-7c5718362ea9'	System	14 Oct 2020 18:18:34
User entered 'No interference with activity (1)'	System	14 Oct 2020 18:18:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-14T13:19:51', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '41bd04a6-cb66-4baf-a311-7c5718362ea9'	System	14 Oct 2020 18:18:34
User entered '14 Oct 2020 13:19'	System	14 Oct 2020 18:18:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:58:57

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:58:57

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 22:37:41
User entered 'Day 14'	System	13 Oct 2020 22:37:41

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-15T12:00:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1f0cd5e0-110c-472b-9a0d-a6f10d26418a'	System	15 Oct 2020 16:59:24
User entered 'No interference with activity (1)'	System	15 Oct 2020 16:59:24

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-15T12:01:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1f0cd5e0-110c-472b-9a0d-a6f10d26418a'	System	15 Oct 2020 16:59:24
User entered '15 Oct 2020 12:01'	System	15 Oct 2020 16:59:24

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:37:41

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:37:41

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:18:34
User entered 'Day 15'	System	14 Oct 2020 18:18:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-16T12:06:37', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '11110eba-730c-4b71-ac48-cca34bf2eea8'	System	16 Oct 2020 17:05:06
User entered 'No interference with activity (1)'	System	16 Oct 2020 17:05:06

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-16T12:06:41', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '11110eba-730c-4b71-ac48-cca34bf2eea8'	System	16 Oct 2020 17:05:06
User entered '16 Oct 2020 12:06'	System	16 Oct 2020 17:05:06

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:18:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:18:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 16:59:24
User entered 'Day 16'	System	15 Oct 2020 16:59:24

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-17T12:37:16', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '154ba016-6cae-4053-8e53-e1c1f7cbfaa7'	System	17 Oct 2020 17:35:40
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:35:40

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-17T12:37:18', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '154ba016-6cae-4053-8e53-e1c1f7cbfaa7'	System	17 Oct 2020 17:35:40
User entered '17 Oct 2020 12:37'	System	17 Oct 2020 17:35:40

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:59:24

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:59:24

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:05:06
User entered 'Day 17'	System	16 Oct 2020 17:05:06

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-18T12:01:43', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cebb41b8-f5ea-47bf-bd3e-9bbb538fad97'	System	18 Oct 2020 17:00:08
User entered 'No interference with activity (1)'	System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-18T12:01:46', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cebb41b8-f5ea-47bf-bd3e-9bbb538fad97'	System	18 Oct 2020 17:00:08
User entered '18 Oct 2020 12:01'	System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:05:06

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:05:06

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 17:35:40
User entered 'Day 18'	System	17 Oct 2020 17:35:40

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-19T13:17:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b3983624-875d-4a03-b6bd-79a36580b02d'	System	19 Oct 2020 18:22:56
User entered 'No interference with activity (1)'	System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-19T13:17:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b3983624-875d-4a03-b6bd-79a36580b02d'	System	19 Oct 2020 18:22:56
User entered '19 Oct 2020 13:17'	System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 17:35:40

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 17:35:40

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 17:00:08
User entered 'Day 19'	System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-20T13:32:08', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b4b91ee3-82dc-4568-a0e4-6b6affb3059a'	System	20 Oct 2020 18:30:31
User entered 'No interference with activity (1)'	System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-20T13:32:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b4b91ee3-82dc-4568-a0e4-6b6affb3059a'	System	20 Oct 2020 18:30:31
User entered '20 Oct 2020 13:32'	System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 18:22:56
User entered 'Day 20'	System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-21T13:21:28', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1a3faefd-869f-4e68-aeb8-3fb13a8e37f7'	System	21 Oct 2020 18:19:49
User entered 'No interference with activity (1)'	System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-21T13:21:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1a3faefd-869f-4e68-aeb8-3fb13a8e37f7'	System	21 Oct 2020 18:19:49
User entered '21 Oct 2020 13:21'	System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 18:30:31
User entered 'Day 21'	System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-22T12:00:20', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c355dcbe-7448-4f6e-ba99-06c4aa2e263f'	System	22 Oct 2020 16:58:43
User entered 'No interference with activity (1)'	System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-22T12:00:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c355dcbe-7448-4f6e-ba99-06c4aa2e263f'	System	22 Oct 2020 16:58:43
User entered '22 Oct 2020 12:00'	System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 18:19:49
User entered 'Day 22'	System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-23T12:00:39', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '14992a9a-3683-4530-b114-f780ebc6f3d5'	System	23 Oct 2020 16:59:04
User entered 'No interference with activity (1)'	System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-23T12:00:44', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '14992a9a-3683-4530-b114-f780ebc6f3d5'	System	23 Oct 2020 16:59:04
User entered '23 Oct 2020 12:00'	System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 16:58:43
User entered 'Day 23'	System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-24T12:24:19', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f7c57f51-3105-4747-9e6b-cc76ed0fd98a'	System	24 Oct 2020 17:22:42
User entered 'No interference with activity (1)'	System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-24T12:24:22', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f7c57f51-3105-4747-9e6b-cc76ed0fd98a'	System	24 Oct 2020 17:22:42
User entered '24 Oct 2020 12:24'	System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 16:59:04
User entered 'Day 24'	System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-25T15:25:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '988b9955-5ce2-4550-823e-12487b43651e'	System	25 Oct 2020 20:23:25
User entered 'No interference with activity (1)'	System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-25T15:25:08', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '988b9955-5ce2-4550-823e-12487b43651e'	System	25 Oct 2020 20:23:25
User entered '25 Oct 2020 15:25'	System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 17:22:42
User entered 'Day 25'	System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 20:23:25
User entered 'Day 26'	System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-27T14:51:24', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '2209a4e2-00ef-4240-ba0f-af4b22f5e409'	System	27 Oct 2020 19:49:38
User entered 'No interference with activity (1)'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-27T14:51:26', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '2209a4e2-00ef-4240-ba0f-af4b22f5e409'	System	27 Oct 2020 19:49:38
User entered '27 Oct 2020 14:51'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:49:38
User entered 'Day 27'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-29T08:45:31', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '6c1c0f19-1d61-44bb-9e51-8d6dd3077d85'	System	29 Oct 2020 13:43:45
User entered 'No interference with activity (1)'	System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-29T08:45:34', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '6c1c0f19-1d61-44bb-9e51-8d6dd3077d85'	System	29 Oct 2020 13:43:45
User entered '29 Oct 2020 08:45'	System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:49:38
User entered 'Day 28'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-29T12:04:23', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1b23f486-8905-45f9-884b-e48de99cba47'	System	29 Oct 2020 17:03:34
User entered 'No interference with activity (1)'	System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-29T12:04:25', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1b23f486-8905-45f9-884b-e48de99cba47'	System	29 Oct 2020 17:03:34
User entered '29 Oct 2020 12:04'	System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Oct 2020 13:43:45
User entered 'Day 29'	System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-30T14:03:40', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '6756b2b2-bf5e-4b6c-bdc6-eb8b80d6f21f'	System	30 Oct 2020 19:01:52
User entered 'No interference with activity (1)'	System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-30T14:03:42', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '6756b2b2-bf5e-4b6c-bdc6-eb8b80d6f21f' User entered '30 Oct 2020 14:03'	System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Oct 2020 17:03:34
User entered 'Day 30'	System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-31T16:10:29', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0a95c3aa-1a82-40a9-9df5-c14f1a6a1986'	System	31 Oct 2020 21:08:43
User entered 'No interference with activity (1)'	System	31 Oct 2020 21:08:43

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-31T16:10:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0a95c3aa-1a82-40a9-9df5-c14f1a6a1986'	System	31 Oct 2020 21:08:43
User entered '31 Oct 2020 16:10'	System	31 Oct 2020 21:08:43

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 19:01:52
User entered 'Day 31'	System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 26 Nov 2020 09:28:29

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-01T16:31:19', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9a90e828-338c-4139-aeef-a0092d970d1f'	System	01 Nov 2020 22:29:34
User entered 'None (0)'	System	01 Nov 2020 22:29:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-01T16:31:22', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9a90e828-338c-4139-aeef-a0092d970d1f'	System	01 Nov 2020 22:29:34
User entered '01 Nov 2020 16:31'	System	01 Nov 2020 22:29:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 19:10:26
User entered 'Day 8'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-09T17:27:05', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8b6304d7-e24c-49cb-a8f3-3b9b784a3d31'	System	09 Oct 2020 22:25:34
User entered 'No (N)'	System	09 Oct 2020 22:25:34

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-09T17:27:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8b6304d7-e24c-49cb-a8f3-3b9b784a3d31'	System	09 Oct 2020 22:25:34
User entered '09 Oct 2020 17:27'	System	09 Oct 2020 22:25:34

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 21:16:26
User entered 'Day 9'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-10T14:04:26', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1cfd5bee-6ae8-4f75-9a59-5977fa60a3bb'	System	10 Oct 2020 19:02:57
User entered 'No (N)'	System	10 Oct 2020 19:02:57

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-10T14:04:29', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '1cfd5bee-6ae8-4f75-9a59-5977fa60a3bb'	System	10 Oct 2020 19:02:57
User entered '10 Oct 2020 14:04'	System	10 Oct 2020 19:02:57

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 22:25:14
User entered 'Day 10'	System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-11T14:23:56', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '4b094bb1-66db-43cd-874c-57326266f2b5'	System	11 Oct 2020 19:22:24
User entered 'No (N)'	System	11 Oct 2020 19:22:24

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-11T14:23:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '4b094bb1-66db-43cd-874c-57326266f2b5'	System	11 Oct 2020 19:22:24
User entered '11 Oct 2020 14:23'	System	11 Oct 2020 19:22:24

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 19:02:39
User entered 'Day 11'	System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-12T12:00:40', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3629c1e2-abb9-4a08-929d-661810513f02'	System	12 Oct 2020 16:59:06
User entered 'No (N)'	System	12 Oct 2020 16:59:06

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-12T12:00:42', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3629c1e2-abb9-4a08-929d-661810513f02'	System	12 Oct 2020 16:59:06
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 16:59:06

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 19:22:05
User entered 'Day 12'	System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-13T17:39:22', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f7ddd7b4-83b3-415d-95e8-98e8a03aad82'	System	13 Oct 2020 22:37:48
User entered 'No (N)'	System	13 Oct 2020 22:37:48

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-13T17:39:25', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f7ddd7b4-83b3-415d-95e8-98e8a03aad82'	System	13 Oct 2020 22:37:48
User entered '13 Oct 2020 17:39'	System	13 Oct 2020 22:37:48

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 16:58:51
User entered 'Day 13'	System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-14T13:19:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '320aad2c-ae2-4586-94cc-6350700d280b'	System	14 Oct 2020 18:18:41
User entered 'No (N)'	System	14 Oct 2020 18:18:41

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-14T13:19:57', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '320aad2c-ae2-4586-94cc-6350700d280b'	System	14 Oct 2020 18:18:41
User entered '14 Oct 2020 13:19'	System	14 Oct 2020 18:18:41

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 22:37:27
User entered 'Day 14'	System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-15T12:01:06', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3cd0ee59-5601-4716-88b3-ba9590124e8c'	System	15 Oct 2020 17:00:09
User entered 'No (N)'	System	15 Oct 2020 17:00:09

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-15T12:01:07', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3cd0ee59-5601-4716-88b3-ba9590124e8c'	System	15 Oct 2020 17:00:09
User entered '15 Oct 2020 12:01'	System	15 Oct 2020 17:00:09

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:18:08
User entered 'Day 15'	System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-16T12:06:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0590dc1d-a95d-46ab-8359-81cafc3ed6fe'	System	16 Oct 2020 17:05:13
User entered 'No (N)'	System	16 Oct 2020 17:05:13

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-16T12:06:51', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0590dc1d-a95d-46ab-8359-81cafc3ed6fe'	System	16 Oct 2020 17:05:13
User entered '16 Oct 2020 12:06'	System	16 Oct 2020 17:05:13

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 16:59:17
User entered 'Day 16'	System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-17T12:37:24', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'dae5313d-fe5b-4e34-bede-8bd94a12bbff'	System	17 Oct 2020 17:36:00
User entered 'No (N)'	System	17 Oct 2020 17:36:00

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-17T12:37:37', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'dae5313d-fe5b-4e34-bede-8bd94a12bbff'	System	17 Oct 2020 17:36:00
User entered '17 Oct 2020 12:37'	System	17 Oct 2020 17:36:00

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:04:53
User entered 'Day 17'	System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-18T12:01:52', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'e287c6f5-4ae8-4436-b8ed-cd623af89506'	System	18 Oct 2020 17:00:13
User entered 'No (N)'	System	18 Oct 2020 17:00:13

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-18T12:01:54', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'e287c6f5-4ae8-4436-b8ed-cd623af89506'	System	18 Oct 2020 17:00:13
User entered '18 Oct 2020 12:01'	System	18 Oct 2020 17:00:13

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	18 Oct 2020 17:00:08
DataPoint Inactivated.	System	18 Oct 2020 16:59:57
Data entry locked.	System	17 Oct 2020 17:35:33
User entered 'Day 18'	System	17 Oct 2020 17:35:33

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-19T13:17:59', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9e7b60de-d79d-46f5-bffd-f1da2c84a890'	System	19 Oct 2020 18:22:58
User entered 'No (N)'	System	19 Oct 2020 18:22:58
DataPoint Activated.	System	18 Oct 2020 17:00:08
DataPoint Inactivated.	System	18 Oct 2020 16:59:57

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-19T13:18:01', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9e7b60de-d79d-46f5-bffd-f1da2c84a890'	System	19 Oct 2020 18:22:58
User entered '19 Oct 2020 13:18'	System	19 Oct 2020 18:22:58
DataPoint Activated.	System	18 Oct 2020 17:00:08
DataPoint Inactivated.	System	18 Oct 2020 16:59:57

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	18 Oct 2020 17:00:08
DataPoint Inactivated.	System	18 Oct 2020 16:59:57
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 17:35:33

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	18 Oct 2020 17:00:08
DataPoint Inactivated.	System	18 Oct 2020 16:59:57
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 17:35:33

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 17:00:08
User entered 'Day 19'	System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-20T13:32:17', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c9b0785d-4a83-4be9-9978-7ca1764a27aa'	System	20 Oct 2020 18:30:41
User entered 'No (N)'	System	20 Oct 2020 18:30:41

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-20T13:32:20', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c9b0785d-4a83-4be9-9978-7ca1764a27aa'	System	20 Oct 2020 18:30:41
User entered '20 Oct 2020 13:32'	System	20 Oct 2020 18:30:41

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 18:22:56
User entered 'Day 20'	System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-21T13:21:35', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8e82c3ce-022c-4e5d-823e-76961c6e673f'	System	21 Oct 2020 18:19:55
User entered 'No (N)'	System	21 Oct 2020 18:19:55

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-21T13:21:37', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '8e82c3ce-022c-4e5d-823e-76961c6e673f' User entered '21 Oct 2020 13:21'	System	21 Oct 2020 18:19:55
	System	21 Oct 2020 18:19:55

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 18:30:31
User entered 'Day 21'	System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-22T12:00:30', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '372afa9b-593c-45ae-bce4-7d3c71484dc3'	System	22 Oct 2020 16:58:53
User entered 'No (N)'	System	22 Oct 2020 16:58:53

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-22T12:00:34', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '372afa9b-593c-45ae-bce4-7d3c71484dc3'	System	22 Oct 2020 16:58:53
User entered '22 Oct 2020 12:00'	System	22 Oct 2020 16:58:53

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 18:19:49
User entered 'Day 22'	System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-23T12:00:48', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '193acd1f-ddf1-4be9-a25c-9b285a155bff'	System	23 Oct 2020 16:59:08
User entered 'No (N)'	System	23 Oct 2020 16:59:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-23T12:00:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '193acd1f-ddf1-4be9-a25c-9b285a155bff'	System	23 Oct 2020 16:59:08
User entered '23 Oct 2020 12:00'	System	23 Oct 2020 16:59:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 16:58:43
User entered 'Day 23'	System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-24T12:24:31', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5022c916-c960-4143-a621-75c4fcc70b'	System	24 Oct 2020 17:22:52
User entered 'No (N)'	System	24 Oct 2020 17:22:52

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-24T12:24:34', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5022c916-c960-4143-a621-75c4fcc70b'	System	24 Oct 2020 17:22:52
User entered '24 Oct 2020 12:24'	System	24 Oct 2020 17:22:52

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 16:59:04
User entered 'Day 24'	System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-25T15:25:13', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c7bdc279-6d22-4d63-bde4-8e15460e9e4c'	System	25 Oct 2020 20:23:32
User entered 'No (N)'	System	25 Oct 2020 20:23:32

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-25T15:25:15', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c7bdc279-6d22-4d63-bde4-8e15460e9e4c'	System	25 Oct 2020 20:23:32
User entered '25 Oct 2020 15:25'	System	25 Oct 2020 20:23:32

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 17:22:42
User entered 'Day 25'	System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 20:23:25
User entered 'Day 26'	System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-27T14:51:30', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e6b5796-090b-4135-b340-3b44b367a8de'	System	27 Oct 2020 19:49:44
User entered 'No (N)'	System	27 Oct 2020 19:49:44

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-27T14:51:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '3e6b5796-090b-4135-b340-3b44b367a8de'	System	27 Oct 2020 19:49:44
User entered '27 Oct 2020 14:51'	System	27 Oct 2020 19:49:44

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:49:38
User entered 'Day 27'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-29T08:45:38', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'bdbab654-93f5-426a-a2ce-3bb95b1ad398'	System	29 Oct 2020 13:43:50
User entered 'No (N)'	System	29 Oct 2020 13:43:50

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-29T08:45:40', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'bdbab654-93f5-426a-a2ce-3bb95b1ad398'	System	29 Oct 2020 13:43:50
User entered '29 Oct 2020 08:45'	System	29 Oct 2020 13:43:50

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:49:38
User entered 'Day 28'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-29T12:04:30', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b0d7ba7e-d6c3-413f-9a7a-d063654ca475'	System	29 Oct 2020 17:03:45
User entered 'No (N)'	System	29 Oct 2020 17:03:45

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-29T12:04:33', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b0d7ba7e-d6c3-413f-9a7a-d063654ca475'	System	29 Oct 2020 17:03:45
User entered '29 Oct 2020 12:04'	System	29 Oct 2020 17:03:45

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Oct 2020 13:43:45
User entered 'Day 29'	System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-30T14:03:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ac6f13a5-6097-4e3a-b49b-1193f28c1469'	System	30 Oct 2020 19:02:04
User entered 'No (N)'	System	30 Oct 2020 19:02:04

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-30T14:03:53', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'ac6f13a5-6097-4e3a-b49b-1193f28c1469'	System	30 Oct 2020 19:02:04
User entered '30 Oct 2020 14:03'	System	30 Oct 2020 19:02:04

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Oct 2020 17:03:34
User entered 'Day 30'	System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-10-31T16:10:40', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cfb4903b-1367-49ae-8187-575291124bfa'	System	31 Oct 2020 21:08:57
User entered 'Yes (Y)'	System	31 Oct 2020 21:08:57

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-10-31T16:10:47', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'cfb4903b-1367-49ae-8187-575291124bfa' User entered '31 Oct 2020 16:10'	System	31 Oct 2020 21:08:57
	System	31 Oct 2020 21:08:57

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 19:01:52
User entered 'Day 31'	System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 09:28:29

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 (0dea248b0b02d5d7)', Time: '2020-11-01T16:31:29', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c5cbca2e-1b25-4191-8082-91068d29f59f'	System	01 Nov 2020 22:29:45
User entered 'Yes (Y)'	System	01 Nov 2020 22:29:45

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 09:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-01T16:31:33', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c5cbca2e-1b25-4191-8082-91068d29f59f' User entered '01 Nov 2020 16:31'	System	01 Nov 2020 22:29:45
	System	01 Nov 2020 22:29:45

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 09:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 09:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 19:01:52

US3492064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	13 Oct 2020 16:51:04

US3492064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Lorna Sanchez McCann (b) (4)	13 Oct 2020 16:51:04

US3492064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	13 Oct 2020 16:51:04

US3492064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	13 Oct 2020 16:51:04

US3492064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:00:34

US3492064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:00:34

US3492064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:00:52

US3492064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:00:52

US3492064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:00:52

US3492064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:00:52

US3492064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	19 Oct 2020 18:46:42

US3492064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 18:46:42

US3492064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	26 Oct 2020 15:42:17
	(b) (4)	

US3492064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Nusirat Williams (b) (4)	26 Oct 2020 15:42:17
	(b) (4)	

US3492064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nusirat Williams (b) (4)	26 Oct 2020 15:42:17

US3492064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:42:17
	(b) (4)	

US3492064

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:42:21

US3492064

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 15:42:21

US3492064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:34:28

US3492064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:34:28

US3492064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Oct 2020 14:34:28

US3492064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	27 Oct 2020 14:34:28

US3492064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:34:34

US3492064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 14:34:34

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 64'	System	04 Sep 2020 18:36:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-04T06:16:25', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '734e399a-578a-4ae8-854d-5055c03e9683'	System	04 Nov 2020 12:16:26
User entered 'Yes (Y)'	System	04 Nov 2020 12:16:26

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-04T06:17:28', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '734e399a-578a-4ae8-854d-5055c03e9683'	System	04 Nov 2020 12:16:26
User entered 'No (N)'	System	04 Nov 2020 12:16:26

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-04T06:16:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '734e399a-578a-4ae8-854d-5055c03e9683'	System	04 Nov 2020 12:16:26
User entered 'No (N)'	System	04 Nov 2020 12:16:26

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-04T06:17:01', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '734e399a-578a-4ae8-854d-5055c03e9683'	System	04 Nov 2020 12:16:26
User entered 'Yes (Y)'	System	04 Nov 2020 12:16:26

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-04T06:17:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '734e399a-578a-4ae8-854d-5055c03e9683'	System	04 Nov 2020 12:16:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 12:16:26

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-04T06:17:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '734e399a-578a-4ae8-854d-5055c03e9683'	System	04 Nov 2020 12:16:26
User entered '04 Nov 2020 06:17:50'	System	04 Nov 2020 12:16:26

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 18:36:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 71'	System	04 Sep 2020 18:36:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-13T12:02:15', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '96fb2ce6-e547-4ff6-a69a-da4a3df08653'	System	13 Nov 2020 18:01:04
User entered 'Yes (Y)'	System	13 Nov 2020 18:01:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-13T12:02:36', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '96fb2ce6-e547-4ff6-a69a-da4a3df08653'	System	13 Nov 2020 18:01:04
User entered 'No (N)'	System	13 Nov 2020 18:01:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-13T12:02:43', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '96fb2ce6-e547-4ff6-a69a-da4a3df08653'	System	13 Nov 2020 18:01:04
User entered 'No (N)'	System	13 Nov 2020 18:01:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-13T12:02:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '96fb2ce6-e547-4ff6-a69a-da4a3df08653'	System	13 Nov 2020 18:01:04
User entered 'Yes (Y)'	System	13 Nov 2020 18:01:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-13T12:02:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '96fb2ce6-e547-4ff6-a69a-da4a3df08653'	System	13 Nov 2020 18:01:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 18:01:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-13T12:02:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '96fb2ce6-e547-4ff6-a69a-da4a3df08653'	System	13 Nov 2020 18:01:04
User entered '13 Nov 2020 12:02:58'	System	13 Nov 2020 18:01:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 18:36:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered 'Day 78'	System	04 Sep 2020 18:36:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-18T03:47:28', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f806ba09-be21-463c-82b9-d1ade517b5da'	System	18 Nov 2020 09:46:00
User entered 'No (N)'	System	18 Nov 2020 09:46:00

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-18T03:47:46', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f806ba09-be21-463c-82b9-d1ade517b5da'	System	18 Nov 2020 09:46:00
User entered 'Yes (Y)'	System	18 Nov 2020 09:46:00

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-18T03:47:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f806ba09-be21-463c-82b9-d1ade517b5da'	System	18 Nov 2020 09:46:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 09:46:00

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-18T03:47:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f806ba09-be21-463c-82b9-d1ade517b5da' User entered '18 Nov 2020 03:47:58'	System	18 Nov 2020 09:46:00

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 18:36:04

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 18:36:04
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 18:36:04

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '01 Nov 2020 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '05 Nov 2020 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-23T08:14:33', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '7434a55d-7f93-4a34-af1d-d784bc3ce0ef'	System	23 Nov 2020 14:12:40
User entered 'No (N)'	System	23 Nov 2020 14:12:40

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-23T08:14:41', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '7434a55d-7f93-4a34-af1d-d784bc3ce0ef'	System	23 Nov 2020 14:12:40
User entered 'No (N)'	System	23 Nov 2020 14:12:40

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-23T08:14:44', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '7434a55d-7f93-4a34-af1d-d784bc3ce0ef'	System	23 Nov 2020 14:12:40
User entered '23 Nov 2020 08:14:44'	System	23 Nov 2020 14:12:40

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 03:55:29

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:55:29
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 03:55:29

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:29

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 20:14:46
	(b) (4)	

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:29

[Time of Contact](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:15:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:15:10
User entered '12:00' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	19 Nov 2020 20:15:10
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:14:46
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 20:14:46

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:29

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 12:00'	System	19 Nov 2020 20:15:10
User entered empty.	System	19 Nov 2020 20:14:46

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:29

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Safety Call (Safety Call)'	Andrea Wendrow (b) (4)	19 Nov 2020 20:14:46

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:29

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 20:14:46

US3492064

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:28:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Elena Llinas (b) (4)	18 Sep 2020 20:29:40
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	08 Sep 2020 15:50:02

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of MUSCLE ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:55:13
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:53:37
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)	29 Oct 2020 18:31:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:31:42
Data point term sent to Coder	System	29 Oct 2020 18:15:54
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'NA - reactogenicity' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 18:15:45
Query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of MUSCLE ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 18:15:22
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 18:15:15
User entered 'generalized MUSCLE ACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:15:15

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of MUSCLE ACHES. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 01:13:41
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:08:32
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)	18 Sep 2020 20:33:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 20:33:43
Data point term sent to Coder	System	18 Sep 2020 20:32:59
User entered 'Muscle Aches'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	19 Nov 2020 19:48:38
User entered 'Yes (Y)'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES ALL OVER BODY on 05 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:52:28
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES ALL OVER BODY on 05 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 18:13:41
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:13:27
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES ALL OVER BODY on 05 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 02:57:31
User entered '6 Sep 2020'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: If the time is unknown, please remove UN:UN and leave the field blank else provide time if known. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 04:32:56
	(b) (4), (b) (6)	20 Nov 2020 17:39:49
Query 'Per CDM re-query: If the time is unknown, please remove UN:UN and leave the field blank else provide time if known. ' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:24:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Nov 2020 14:23:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 14:23:43
User closed query 'Per CDM: The Treatment 1 was given on 04 SEP 2020 and AE start date is 05 SEP 2020. Per CCGs, start time is the required field if the AE started within 24 hours of dosing. Please provide the start time else if AE started after 24 hrs of dosing confirm in query response. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:02:40
User opened query 'Per CDM re-query: If the time is unknown, please remove UN:UN and leave the field blank else provide time if known. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:02:38
Query 'Per CDM: The Treatment 1 was given on 04 SEP 2020 and AE start date is 05 SEP 2020. Per CCGs, start time is the required field if the AE started within 24 hours of dosing. Please provide the start time else if AE started after 24 hrs of dosing confirm in query response. Thank you' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	19 Nov 2020 19:48:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Nov 2020 19:48:38
User entered 'un:un' (non-conformant).	Andrea Wendrow (b) (4)	19 Nov 2020 19:48:38
User opened query 'Per CDM: The Treatment 1 was given on 04 SEP 2020 and AE start date is 05 SEP 2020. Per CCGs, start time is the required field if the AE started within 24 hours of dosing. Please provide the start time else if AE started after 24 hrs of dosing confirm in query response. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:52:01

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 12:54:56
Query 'Data is required. Please provide.' answered with 'not required' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 18:14:43
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Oct 2020 18:13:27
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 14:23:43
User entered '05 Sep 2020 UN:UN' (non-conformant).	System	19 Nov 2020 19:48:38
User entered empty.	System	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)' reason for change: New Information	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 19:46:38
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Per CDM: Thank you for your response. However Outcome is recorded as Not Recovered/Not Resolved and End date is present. Please review and reconcile responses. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:33:09
Query 'Per CDM: Thank you for your response. However Outcome is recorded as Not Recovered/Not Resolved and End date is present. Please review and reconcile responses. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 18:14:54
User entered '23 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 18:13:27
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:10:08
User opened query 'Per CDM: Thank you for your response. However Outcome is recorded as Not Recovered/Not Resolved and End date is present. Please review and reconcile responses. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:10:07
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'on safety call day 22 subject stated the muscle aches ended on 18/09/20 ' (Site from System).	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 19:48:39
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Sep 2020 19:46:38
User entered '18 Sep 2020' reason for change: New Information	Elena Llinas (b) (4) (b) (4)	25 Sep 2020 19:46:38
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 12:33:40
Query 'Data is required. Please provide.' answered with 'not required' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 18:14:49
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Oct 2020 18:13:27
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:04:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:04:10
User entered 'Related (RELATED)' reason for change: Per Query Resolution	Elena Llinas (b) (4)	18 Sep 2020 21:04:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:32:07
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:04:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:04:10
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Elena Llinas (b) (4)	18 Sep 2020 21:04:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:32:07
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:04:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:04:10
User entered 'None (NONE)' reason for change: Data Entry Error	Elena Llinas (b) (4)	18 Sep 2020 21:04:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:32:07
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '1'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:13:27
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:04:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:04:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 21:04:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:32:07
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 20:32:07

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:19:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:19:04
Data point term sent to Coder	System	26 Oct 2020 15:46:53
User entered 'Joint Aches'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '4 Sep 2020'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 17:47:21
Query 'Data is required. Please provide.' answered with 'UNK' (Site from System).	Nusirat Williams (b) (4)	26 Oct 2020 15:46:16
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 15:45:54
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Related (RELATED)'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Related (RELATED)'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 15:46:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 15:46:25
User entered 'None (NONE)' reason for change: Data Entry Error	Nusirat Williams (b) (4)	26 Oct 2020 15:46:25
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 15:45:54
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '1'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4)	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 15:45:54

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:12
User entered 'USA-US101-2020-mRNA-1273-P301000004'	System	03 Nov 2020 20:32:17
User entered 'New'	(b) (4), (b) (6)	03 Nov 2020 20:32:17

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:42:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 20:42:03
Data point term sent to Coder	System	19 Nov 2020 20:40:57
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:40:18
User entered 'CEREBROVASCULAR ACCIDENT' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:40:18
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 06:02:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 06:02:13
Data point term sent to Coder	System	02 Nov 2020 23:48:38
User entered 'Possible Cerebrovascular accident'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '31 Oct 2020' reason for change: New Information	Andrea Wendrow (b) (4)	19 Nov 2020 19:54:49
User entered '30 Oct 2020'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Nov 2020 23:48:41
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:41
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Nov 2020 23:48:15
User entered '02:00'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 23:48:41
User entered '30 Oct 2020 02:00'	System	02 Nov 2020 23:48:15

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4)	19 Nov 2020 19:54:49
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 20:40:18
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Nov 2020 20:40:18
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 19:54:49
User entered '11 Nov 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	19 Nov 2020 19:54:49
User entered empty.	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:27:13
	(b) (4), (b) (6)	20 Nov 2020 17:39:49
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	19 Nov 2020 23:00:42
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	19 Nov 2020 23:00:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Nov 2020 23:00:16
User entered empty; reason for change Per Query Resolution	Andrea Wendrow (b) (4)	19 Nov 2020 23:00:16
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Nov 2020 22:59:28
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	19 Nov 2020 22:59:28
User entered 'un:un' (non-conformant).	Andrea Wendrow (b) (4)	19 Nov 2020 22:59:28
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:31:32
	(b) (4), (b) (6)	
User entered empty.	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:00:16
User entered '11 Nov 2020 UN:UN' (non-conformant).	System	19 Nov 2020 22:59:28
User entered empty.	System	02 Nov 2020 23:48:15

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 04:32:30
	(b) (4), (b) (6)	20 Nov 2020 17:39:49
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'admission date is listed below. Currently awaiting information and outcome' (Site from System).	Andrea Wendrow (b) (4)	02 Nov 2020 23:49:35
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	02 Nov 2020 23:48:15
User entered '1'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '31 Oct 2020'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '11 Nov 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4)	19 Nov 2020 19:34:07
User entered empty.	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Nov 2020 19:34:07
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		19 Nov 2020 19:34:07
User entered 'Yes (Y)' reason for change: New Information	Marla Schwarber (b) (4)	19 Nov 2020 19:34:07
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	02 Nov 2020 23:48:15
User entered 'Unknown (UNK)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '11' reason for change: New Information	Marla Schwarber (b) (4)	19 Nov 2020 19:34:07
User entered empty.	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '1' reason for change: Per Query Resolution	Marla Schwarber (b) (4)	19 Nov 2020 19:34:07
User entered '0'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Since the last dose of study drug was administered on 02 Oct 2020, please consider updating the action taken from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:26:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
Query 'PV Query: Since the last dose of study drug was administered on 02 Oct 2020, please consider updating the action taken from none to not applicable. ' answered with 'changed per request' (Site from Safety).	Marla Schwarber (b) (4)	19 Nov 2020 19:34:51
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4)	19 Nov 2020 19:34:07
User opened query 'PV Query: Since the last dose of study drug was administered on 02 Oct 2020, please consider updating the action taken from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:30:31
User entered 'None (NONE)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 19:34:07
Comment added 'Pending until we receive requested medical records'.	Andrea Wendrow (b) (4)	10 Nov 2020 23:09:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Nov 2020 23:48:15
User entered '0'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '1' reason for change: New Information	Marla Schwarber (b) (4)	19 Nov 2020 19:34:07
User entered '0'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:27:46
	(b) (4), (b) (6)	20 Nov 2020 17:39:49
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'Resolution expected' (Site from Safety).	Marla Schwarber (b) (4)	19 Nov 2020 20:47:31
	(b) (4)	
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Marla Schwarber (b) (4)	19 Nov 2020 20:40:18
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Marla Schwarber (b) (4)	19 Nov 2020 19:34:07
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:33:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	19 Nov 2020 20:41:10
User entered 'right lower extremity weakness' reason for change: New Information	Marla Schwarber (b) (4)	19 Nov 2020 20:41:10
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	19 Nov 2020 20:40:18
	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:28:10
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:28:03
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:27:53
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:27:24
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:26:34
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:26:22
User closed query 'PV Query: Please clarify if this is a confirmed diagnosis of Symptomatic Covid-19 and report if applicable. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:25:46
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Records faxed 19NOV2020' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 22:53:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'Records faxed 19NOV2020' (Site from Safety).	Marla Schwarber (b) (4)	19 Nov 2020 22:53:43
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'Records faxed 19NOV2020' (Site from Safety).	Marla Schwarber (b) (4)	19 Nov 2020 22:53:37
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'completed' (Site from Safety).	Andrea Wendrow (b) (4)	19 Nov 2020 20:17:42
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'no known exposure' (Site from Safety).	Andrea Wendrow (b) (4)	19 Nov 2020 20:17:34
Query 'PV Query: Please clarify if this is a confirmed diagnosis of Symptomatic Covid-19 and report if applicable. ' answered with 'no, subject asymptomatic' (Site from Safety).	Andrea Wendrow (b) (4)	19 Nov 2020 20:12:40
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Discharge date provided' (Site from Safety).	Marla Schwarber (b) (4)	19 Nov 2020 19:35:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:34:31
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:34:15
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:33:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:32:05
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:31:03
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:30:51
User opened query 'PV Query: Please clarify if this is a confirmed diagnosis of Symptomatic Covid-19 and report if applicable. ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:30:13
User entered 'Participant phoned study site on 02Nov2020 to report that had been admitted on 31Oct2020 to outside hospital after having "massive headache and the feeling of loss of use of right leg" on that began 30Oct2020. Additionally reported that were diagnosed COVID-19 positive upon admission. Awaiting further details of hospitalization'	Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:28:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 19:34:07
User entered '0'	System	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:26:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:26:05
Data point term sent to Coder	System	19 Nov 2020 21:10:41
User entered 'Asymptomatic COVID-19 infection'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'PV Query Urgent: Please confirm event is of SYMPTOMATIC COVID-19. If so, please update event term to 'COVID-19'. If not, please change answer to 'NO' and consider deleting per protocol reporting criteria.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:18:57
	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4)	20 Nov 2020 17:06:06
Query 'PV Query Urgent: Please confirm event is of SYMPTOMATIC COVID-19. If so, please update event term to 'COVID-19'. If not, please change answer to 'NO' and consider deleting per protocol reporting criteria.' answered with 'This documentation was done on guidance from our PPD monitor' (Site from Safety).	Marla Schwarber (b) (4)	20 Nov 2020 16:11:02
User opened query 'PV Query Urgent: Please confirm event is of SYMPTOMATIC COVID-19. If so, please update event term to 'COVID-19'. If not, please change answer to 'NO' and consider deleting per protocol reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 14:38:51
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '31 Oct 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 21:10:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	19 Nov 2020 21:10:51
User entered '11 Nov 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:51
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	19 Nov 2020 21:10:34
User entered '11 Oct 2020'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 21:10:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '1'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34
	(b) (4)	

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'subject hospitalized for CVA (see other AE) and at time of admission a COVID RT-PCR was found to be positive. Subject remained asymptomatic throughout hospitalization'	Andrea Wendrow (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:28:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 21:10:34

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:28:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:50:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:24:43
Data point term sent to Coder	System	29 Oct 2020 15:57:09
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 15:56:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:01:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:01:52
Data point term sent to Coder	System	08 Sep 2020 16:00:56
User entered 'atorvastatin'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User closed query 'Per DM CLR: Please update the indication to reflect the condition/diagnosis related to CHOLESTEROL. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:58:15
Query 'Per DM CLR: Please update the indication to reflect the condition/diagnosis related to CHOLESTEROL. Please reconcile with Med History eCRF as appropriate. ' answered with 'updated per medical history form' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:57:10
User entered 'CHOLESTEROL - hyperlipidemia' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 15:56:54
User opened query 'Per DM CLR: Please update the indication to reflect the condition/diagnosis related to CHOLESTEROL. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:53:06
User entered 'cholesterol'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '40'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 16:03:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 16:03:45
Data point term sent to Coder	System	08 Sep 2020 16:02:58
User entered 'metformin'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'diabetes'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '850'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'twice daily (BID)'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '02 Oct 2019'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 16:02:09

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:03:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:03:45
Data point term sent to Coder	System	08 Sep 2020 16:03:01
User entered 'vitamin b-12'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'supplement'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '1000'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User closed query 'Per CDM: Thank you for your response. MCG is equivalent to 'ug'. Since 'ug' is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:23:04
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	17 Sep 2020 14:51:41
Query 'Per CDM: Thank you for your response. MCG is equivalent to 'ug'. Since 'ug' is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 14:51:25
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	17 Sep 2020 14:51:16
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:51:16
User closed query 'Per DM: 'Dose Unit' is 'Other and 'If dose unit is Other, specify' is entered as 'MCG '. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required, else provide an explanation.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:23:04
User opened query 'Per CDM: Thank you for your response. MCG is equivalent to 'ug'. Since 'ug' is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:23:01
Query 'Per DM: 'Dose Unit' is 'Other and 'If dose unit is Other, specify' is entered as 'MCG '. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required, else provide an explanation.' answered with 'the chart specified 1000 mcg. mcg is not an option' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 13:42:10

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
User opened query 'Per DM: 'Dose Unit' is 'Other and 'If dose unit is Other, specify' is entered as 'MCC'. Please confirm if any other suitable predefined option is available under the data field 'Dose unit' for this medication and update as required, else provide an explanation.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:57:18
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:51:41
User entered 'mcg'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'un UNK 2017'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 16:02:57

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:04:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:04:50
Data point term sent to Coder	System	08 Sep 2020 16:04:02
User entered 'vitamin c'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'supplement'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '500'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'un UNK 2017'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 16:03:32

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: ERYTHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:30:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:30:10
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	29 Oct 2020 15:58:10 29 Oct 2020 15:57:32
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: ERYTHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:20:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:20:47
Data point term sent to Coder User entered 'erythromycin'	System (b) (4), (b) (6)	08 Sep 2020 16:05:05 08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 13:01:17
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'updated per medical history form' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:57:47
User entered 'RUNNY EYE ISSUE - corneal abrasion' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 15:57:32
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:53:26
User entered 'runny eye issue'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '1'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'application'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'other (OTHER)'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User closed query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'RIGHT EYE AT BEDTIME'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:25:47
Query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'RIGHT EYE AT BEDTIME'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' answered with 'no predefined option is suitable' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 13:43:03
User opened query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'RIGHT EYE AT BEDTIME'. Please confirm if any other suitable predefined option is available under the data field 'Frequency' for this medication and update as required. Otherwise please provide explanation.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 18:13:44
User entered 'right eye at bedtime'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '12 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:28:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:28:46
Data point term sent to Coder	System	02 Oct 2020 18:27:10
User entered 'tamsulosin'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'BPH'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0.4'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'un Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:26:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:47:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:47:03
Data point term sent to Coder	System	19 Nov 2020 20:20:21
User entered 'aspirin'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'ASCVD prophylaxis'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '81'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '31 Oct 2020'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 20:19:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:47:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:47:48
Data point term sent to Coder	System	19 Nov 2020 20:28:34
User entered 'clopidogrel'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'ASCVD prophylaxis'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '75'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '31 Oct 2020'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 04:00:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 04:00:54
Data point term sent to Coder	System	19 Nov 2020 20:31:39
User entered 'Heparin'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'thrombus prophylaxis'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '5000'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Other (OTHER)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'units'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Subcutaneous (SUBCUTANEOUS)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '31 Oct 2020'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '11 Nov 2020'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:35:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:35:02
Data point term sent to Coder	System	19 Nov 2020 20:34:43
User entered 'Miralax'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Prevent constipation'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '17'	Marla Schwarber (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'g (g)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	Marla Schwarber (b) (4)	19 Nov 2020 20:33:58
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '31 Oct 2020'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	Marla Schwarber (b) (4)	19 Nov 2020 20:33:58
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '11 Nov 2020'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:38:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:38:05
Data point term sent to Coder	System	19 Nov 2020 20:36:48
User entered 'senokot'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'prevent constipation'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '2'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'tablet (TABLET)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4)	19 Nov 2020 20:35:46
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '31 Oct 2020'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	Marla Schwarber (b) (4)	19 Nov 2020 20:35:46
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '11 Nov 2020'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:28:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:50:09

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'USA-US101-2020-MRNA-1273-P301000004'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Yes (Y)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Yes (Y)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 23:28:39
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Un-reviewed for Safety.	System	19 Nov 2020 19:34:07
User entered 'Yes (Y)'	System	19 Nov 2020 19:34:07
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Richard'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Novak'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered '808 S. Wood St'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Chicago'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'IL'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered '60612'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 23:28:39
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
User entered 'US'	System	03 Nov 2020 20:33:56

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 23:29:04
User entered '1'	System	03 Nov 2020 20:33:56

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'USA-US101-2020-MRNA-1273-P301000004'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Yes (Y)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Yes (Y)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 23:28:39
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Un-reviewed for Safety.	System	19 Nov 2020 19:34:07
User entered 'Yes (Y)'	System	19 Nov 2020 19:34:07
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Richard'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Novak'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered '808 S. Wood St'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Chicago'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'IL'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered '60612'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 23:28:39
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
User entered 'US'	System	03 Nov 2020 20:33:56

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 23:29:04
User entered '1'	System	03 Nov 2020 20:33:56

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:28:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
User entered '03/Nov/2020 20:33'	System	03 Nov 2020 20:33:56

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:28:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 23:28:39
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 20:33:56

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'USA-US101-2020-MRNA-1273-P301000004'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Yes (Y)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Yes (Y)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 23:28:39
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Un-reviewed for Safety.	System	19 Nov 2020 19:34:07
User entered 'Yes (Y)'	System	19 Nov 2020 19:34:07
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'No (N)'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Richard'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Novak'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered '808 S. Wood St'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'Chicago'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered 'IL'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 20:33:43
User entered '60612'	System	03 Nov 2020 20:32:17

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 23:28:39
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
User entered 'US'	System	03 Nov 2020 20:33:56

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Nov 2020 23:29:04
User entered '1'	System	03 Nov 2020 20:33:56

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:28:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '20/Nov/2020 18:29'	System	20 Nov 2020 23:29:04

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:28:29

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)	20 Nov 2020 23:29:04