

US3492064 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:55:38

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US3492064

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

[Participant ID](#)

US3492064

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

US3492064

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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

Data signed: (b) (4) 15 Feb 2021 03:36:18

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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 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 03:36:18

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 03:36:18

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Condition	RIGHT LOWER EXTREMITY WEAKNESS
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:36:18

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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

Data signed: (b) (4) 15 Feb 2021 03:36:18

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 03:36:18

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
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)

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

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

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 07:55:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☒
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☒
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 16

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 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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
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)

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
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

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

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

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 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

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 OCT 2020

Collection time (00:00-23:59)

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

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Collection date (dd MMM yyyy)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	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

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 10 Jun 2021 07:55:38

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

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

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 10 Jun 2021 07:55:38

TIMEPOINT

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

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 OCT 2020 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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 31
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3492064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:36:19

Generated On: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	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: 10 Jun 2021 07:55:38

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	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: 10 Jun 2021 07:55:38

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

Please 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 09:20:53

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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 09:44:55
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 13:10:32

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 08:49:27

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 02:23:24

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 JAN 2021 15:37:25

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 16:30:55

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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	17 JAN 2021 05:17:21
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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 JAN 2021 15:27:47
Patient Cloud Open Date & Time	24 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	210 of 2801

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	31 JAN 2021 12:36:04
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 06:44:34

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 23:01:08

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 04:06:36

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 05:15:41

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 18:40:38

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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 08:33:28
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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 01:35:48

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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 09:50:01

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: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 APR 2021 08:59:03
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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 474

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 MAR 2022 00:01
Patient Cloud Close Date & Time	24 MAR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:55:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 05:15:54

US3492064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 NOV 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 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 DEC 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 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 JAN 2021

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 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:40:56

Generated On: 10 Jun 2021 07:55:38

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

Visit date (dd MMM yyyy)	17 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 10:19
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:40:56

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

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

US3492064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 01:40:56

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	10:20 (24 HR)
Collection date and time (derived)	17 MAR 2021 10:20

US3492064

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:40:56

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

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 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3492064

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3492064

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3492064

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Height	
Weight	
BMI (xxx.x)	

US3492064

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	13:47 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 13:47
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3492064

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	15:16 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 15:16
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 14:45 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 14:45

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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	13:51 (24 HR)
Collection date and time (derived)	14 JAN 2021 13:51

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	14:00
Collection Date and Time (derived)	14 JAN 2021 14:00

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

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 OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3492064

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 10:20
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 11:20
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3492064

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3492064

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 FEB 2021

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 10:50

Which arm was used to give treatment? Left Arm ☐ Right Arm ☒

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3492064

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

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 OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492064

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:19 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 10:19
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492064

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3492064

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 01:40:55

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	17 MAR 2021
Collection time (<i>00:00-23:59</i>)	10:20 (24 HR)
Collection date and time (derived)	17 MAR 2021 10:20

US3492064

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

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)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

AEID	
Adverse event	GENERALIZED JOINT ACHES
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	5 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT REPORTS 28JAN2021 THAT WHILE ACHES ARE STILL GENERALIZED, THE FOCAL POINT IS NOW HIS RIGHT SHOULDER AND THE ACHES ELSEWHERE ARE IMPROVING.
Serious Adverse Event Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

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)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

AEID	USA-US101-2020-MRNA-1273-P30 1000004
Adverse event	CEREBROVASCULAR ACCIDENT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	11 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

Number of Days in ICU	11
Persistent or significant disability or incapacity	True
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	RIGHT LOWER EXTREMITY WEAKNESS

Narrative

US3492064

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

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)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

AEID	
Adverse event	ASYMPTOMATIC COVID-19 INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 16:22:53

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

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
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 16:22:53

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AEID

Adverse event

GENERAL 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)

03 OCT 2020

Start time (00:00-23:59)

12:00 (24 HR)

AE start date and time (derived)

03 OCT 2020 12:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 OCT 2020

End time (00:00-23:59)

12:00 (24 HR)

AE End Date and Time (derived)

17 OCT 2020 12:00

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 16:22:53

Generated On: 10 Jun 2021 07:55:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	REPORTED IN DIARY DOSE 2
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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 03:36:18

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Feb 2021 03:36:17

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Feb 2021 03:36:17

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

Name of Medication ERYTHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication RUNNY EYE ISSUE DUE TO
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

Name of Medication CLOPIDOGREL

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

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 ☐

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EAB) (1725)

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

Name of Medication SENOKOT

Prophylaxis Yes ☒
No ☐

Indication PREVENT CONSTIPATION

Dose per administration 17.2

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PREVENT INFLUENZA
Dose per administration	UNK
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNK
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

Name of Medication SHINGLES SHOT

Prophylaxis Yes ☒
No ☐

Indication PREVENT SHINGLES

Dose per administration UNK

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNK

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Feb 2021 03:36:17

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3492064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3492064

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:55:38

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US101-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US101-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
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)

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US101-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
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

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Feb 2021 03:36:18

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US101-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	01/DEC/2020 13:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3492064 (Prod: UIC Project WISH CRS)

US3492064

Form: Participant Creation

Generated On: 10 Jun 2021 07:55:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'US3492064'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 15:54:55

US3492064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:52:42

US3492064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '04 SEP 2020'	RWS_ENDPOINT	04 Sep 2020 15:54:56
	ENDPOINT (b) (4)	
	(b) (4)	

US3492064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:52:42

US3492064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'SCRN'	(b) (4), (b) (6) System	04 Sep 2020 17:52:42

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered (b) (6) 1961'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 15:54:57

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '59'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'YEARS'	(b) (4), (b) (6) System	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered '59'	(b) (4), (b) (6) System	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Male (M)'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 17:53:40

US3492064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '04 Sep 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4)	10 Nov 2020 20:54:55
	(b) (4)	
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'Sep 2020'	(b) (4), (b) (6) System	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered '2020'	(b) (4), (b) (6) System	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:54:01

US3492064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	RWS_ENDPOINT	04 Sep 2020 15:54:56
	ENDPOINT (b) (4)	
	(b) (4)	

US3492064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'I'	(b) (4), (b) (6) System	04 Sep 2020 17:55:31

US3492064

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:55:38

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:55:31

US3492064

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:55:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:35:24

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'un May 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'May 2020'	(b) (4), (b) (6) System	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered '2020'	(b) (4), (b) (6) System	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 15:36:04

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
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.	(b) (4) 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)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'Jan 2018'	(b) (4), (b) (6) System	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered '2018'	(b) (4), (b) (6) System	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 15:36:34

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
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.	(b) (4) Coder Import (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)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'Jan 2017'	(b) (4), (b) (6) System	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered '2017'	(b) (4), (b) (6) System	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 15:40:16

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'Jan 2020'	(b) (4), (b) (6) System	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered '2020'	(b) (4), (b) (6) System	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 15:42:22

US3492064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 18:59:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 18:59:55
	(b) (4)	
Data point term sent to Coder	System	11 Dec 2020 18:58:48
User entered 'BPH'	(b) (4), (b) (6)	11 Dec 2020 18:58:34

US3492064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'UN Jun 2020'	(b) (4), (b) (6)	11 Dec 2020 18:58:34

US3492064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:58:34

US3492064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:58:34

US3492064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:58:34

US3492064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 18:58:34

US3492064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'Jun 2020'	(b) (4), (b) (6) System	11 Dec 2020 18:58:34

US3492064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered '2020'	(b) (4), (b) (6) System	11 Dec 2020 18:58:34

US3492064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered empty.	(b) (4), (b) (6) System	11 Dec 2020 18:58:34

US3492064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered empty.	(b) (4), (b) (6) System	11 Dec 2020 18:58:34

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '11:04'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered '04 Sep 2020 11:04'	(b) (4), (b) (6) System	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '176.9' cm	(b) (4) (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: 10 Jun 2021 07:55:38

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '96.3' kg	(b) (4) (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: 10 Jun 2021 07:55:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered '30.77306'	(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: 10 Jun 2021 07:55:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'kg/m2'	(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: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:59:44
Query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' answered with '-----corrected-----' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 20:26:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 20:26:19
User opened query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 16:35:44
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'bpm'	(b) (4), (b) (6) System	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 15:45:03

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 06:21:59

US3492064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 06:21:59

US3492064

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:45:20

US3492064

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:20

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:21:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 18:41:37

US3492064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '04 Sep 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4)	10 Nov 2020 20:54:18
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'VISIT1'	(b) (4), (b) (6) System	04 Sep 2020 17:54:24

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 17:09:22

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '145868'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 17:09:22

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 17:09:22

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:55:04

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:55:04

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 17:55:04

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 17:55:04

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 17:55:04

US3492064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
Amendment Manager: DataPoint set to visible.	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
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) (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: 10 Jun 2021 07:55:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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

Generated On: 10 Jun 2021 07:55:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
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) (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: 10 Jun 2021 07:55:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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 (1)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
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: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '04 Sep 2020 11:04'	(b) (4), (b) (6) System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'bpm'	(b) (4), (b) (6) System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '127'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '79'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
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) (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: 10 Jun 2021 07:55:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
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: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '13:29'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '04 Sep 2020 13:29'	(b) (4), (b) (6) System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'bpm'	(b) (4), (b) (6) System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '117'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 15:47:17

US3492064

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '12:58'	(b) (4), (b) (6)	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '4 Sep 2020 12:58'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'ONCE'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '04 Sep 2020 12:17'	(b) (4), (b) (6) System	08 Sep 2020 15:47:58

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
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: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '04 Sep 2020 12:30'	(b) (4), (b) (6) System	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:55:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
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: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 15:48:26

US3492064

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:48:32

US3492064

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '1'	(b) (4), (b) (6) System	08 Sep 2020 15:48:32

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered '98.3'	(b) (4), (b) (6) System	04 Sep 2020 18:43:48
	System	04 Sep 2020 18:43:48

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Sep 2020 13:18'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Sep 2020 15:48'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Sep 2020 16:43'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) System	10 Sep 2020 10:45:20
User entered '10 Sep 2020 05:46'	System	10 Sep 2020 10:45:20

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Sep 2020 13:18'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Sep 2020 15:48'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Sep 2020 16:43'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Sep 2020 13:47:38

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'No (N)'	System	07 Sep 2020 12:44:12

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered '08 Sep 2020 06:03'	(b) (4), (b) (6) System	08 Sep 2020 11:02:00
	System	08 Sep 2020 11:02:00

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'None (0)'	System	04 Sep 2020 18:46:43

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	04 Sep 2020 18:46:43

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Sep 2020 13:18'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Sep 2020 15:48'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Sep 2020 16:43'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Sep 2020 11:03:33

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered 'None (0)'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered 'None (0)'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	04 Sep 2020 18:36:04

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 13:16:30

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 13:16:30

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	19 Sep 2020 12:18:05

US3492064

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	19 Sep 2020 12:18:05

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	12 Sep 2020 13:25:55

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	12 Sep 2020 13:25:55

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	13 Sep 2020 10:39:50

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	13 Sep 2020 10:39:50

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 12:12:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 12:12:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	15 Sep 2020 11:24:43

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	15 Sep 2020 11:24:43

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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-4416-8df5-5696bfdb448f' User entered '18 Sep 2020 08:17'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 10:59:45

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 10:59:45

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 14:37:01

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 14:37:01

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 13:16:38

US3492064

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 13:16:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	10 Sep 2020 10:47:18

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'No (N)'	System	13 Sep 2020 10:40:02

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 11:22:11

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	12 Sep 2020 13:25:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	13 Sep 2020 10:39:15

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 12:12:32

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	15 Sep 2020 11:24:32

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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-57ce19cdf17'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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-57ce19cdf17'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 10:59:38

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Sep 2020 12:18:18

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 14:36:31

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	18 Sep 2020 13:16:30

US3492064

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	18 Sep 2020 13:16:30

US3492064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	Elena Llinas (b) (4)	11 Sep 2020 16:52:37
	(b) (4)	

US3492064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '11 Sep 2020'	(b) (4) Elena Llinas (b) (4) (b) (4)	11 Sep 2020 16:52:37

US3492064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elena Llinas (b) (4)	11 Sep 2020 16:52:37

US3492064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Elena Llinas (b) (4)	11 Sep 2020 16:52:37
	(b) (4)	

US3492064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	Elena Llinas (b) (4)	11 Sep 2020 16:52:41
	(b) (4)	

US3492064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'I'	(b) (4), (b) (6) System	11 Sep 2020 16:52:41

US3492064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Elena Llinas (b) (4) (b) (4)	18 Sep 2020 19:56:28

US3492064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '18 Sep 2020'	(b) (4) Elena Llinas (b) (4) (b) (4)	18 Sep 2020 19:56:28

US3492064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elena Llinas (b) (4)	18 Sep 2020 19:56:28

US3492064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 19:56:28
	(b) (4)	

US3492064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	Elena Llinas (b) (4)	18 Sep 2020 19:56:34
	(b) (4)	

US3492064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'I'	(b) (4), (b) (6) System	18 Sep 2020 19:56:34

US3492064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	Elena Llinas (b) (4)	25 Sep 2020 20:15:45
	(b) (4)	

US3492064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '25 Sep 2020'	(b) (4) Elena Llinas (b) (4) (b) (4)	25 Sep 2020 20:15:45

US3492064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elena Llinas (b) (4) (b) (4)	25 Sep 2020 20:15:45

US3492064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Elena Llinas (b) (4)	25 Sep 2020 20:15:45
	(b) (4)	

US3492064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	Elena Llinas (b) (4)	25 Sep 2020 20:15:49
	(b) (4)	

US3492064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'I'	(b) (4), (b) (6) System	25 Sep 2020 20:15:49

US3492064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'VISIT2'	(b) (4), (b) (6) System	02 Oct 2020 16:30:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
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: 10 Jun 2021 07:55:38

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '62'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'bpm'	(b) (4), (b) (6) System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'breaths/min'	(b) (4), (b) (6) System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '131'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'mmHg'	(b) (4), (b) (6) System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'mmHg'	(b) (4), (b) (6) System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
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: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '02 Oct 2020 12:50'	(b) (4), (b) (6) System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'bpm'	(b) (4), (b) (6) System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'breaths/min'	(b) (4), (b) (6) System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'mmHg'	(b) (4), (b) (6) System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'mmHg'	(b) (4), (b) (6) System	02 Oct 2020 18:23:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '2 Oct 2020 12:20'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'ONCE'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '02 Oct 2020 10:50'	(b) (4), (b) (6) System	02 Oct 2020 18:24:11

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
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: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (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: 10 Jun 2021 07:55:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '02 Oct 2020 11:00'	(b) (4), (b) (6) System	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:55:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
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: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered empty.	(b) (4), (b) (6) System	02 Oct 2020 18:24:22

US3492064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '1'	(b) (4), (b) (6) System	02 Oct 2020 17:54:06

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'No (N)'	System	02 Oct 2020 17:55:37

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered '02 Oct 2020 12:57'	(b) (4), (b) (6) System	02 Oct 2020 17:55:37
	System	02 Oct 2020 17:55:37

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Oct 2020 12:40'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Oct 2020 15:10'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Oct 2020 16:05'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered '96.6'	(b) (4), (b) (6) System	04 Oct 2020 17:21:21
	System	04 Oct 2020 17:21:21

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered '97.8'	(b) (4), (b) (6) System	05 Oct 2020 18:10:58
	System	05 Oct 2020 18:10:58

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	07 Oct 2020 19:08:04

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered '98.2'	(b) (4), (b) (6) System	07 Oct 2020 19:08:04
	System	07 Oct 2020 19:08:04

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered '07 Oct 2020 14:09'	(b) (4), (b) (6) System	07 Oct 2020 19:08:04
	System	07 Oct 2020 19:08:04

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Oct 2020 12:40'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Oct 2020 15:10'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Oct 2020 16:05'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Oct 2020 12:40'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Oct 2020 15:10'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Oct 2020 16:05'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '05 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '07 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '08 Oct 2020 12:00'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Oct 2020 11:59'	(b) (4), (b) (6) System	02 Oct 2020 17:53:57

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Oct 2020 12:00'	(b) (4), (b) (6) System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Oct 2020 11:59'	(b) (4), (b) (6) System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Oct 2020 12:00'	(b) (4), (b) (6) System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Oct 2020 11:59'	(b) (4), (b) (6) System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Oct 2020 12:00'	(b) (4), (b) (6) System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '19 Oct 2020 11:59'	(b) (4), (b) (6) System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 22:25:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 22:25:26

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	10 Oct 2020 19:02:46

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	10 Oct 2020 19:02:46

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	11 Oct 2020 19:22:12

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	11 Oct 2020 19:22:12

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	12 Oct 2020 16:58:57

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	12 Oct 2020 16:58:57

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 22:37:41

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 22:37:41

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Oct 2020 12:00'	(b) (4), (b) (6) System	14 Oct 2020 18:18:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Oct 2020 11:59'	(b) (4), (b) (6) System	14 Oct 2020 18:18:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Oct 2020 12:00'	(b) (4), (b) (6) System	15 Oct 2020 16:59:24

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Oct 2020 11:59'	(b) (4), (b) (6) System	15 Oct 2020 16:59:24

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Oct 2020 12:00'	(b) (4), (b) (6) System	16 Oct 2020 17:05:06

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '19 Oct 2020 11:59'	(b) (4), (b) (6) System	16 Oct 2020 17:05:06

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '19 Oct 2020 12:00'	(b) (4), (b) (6) System	17 Oct 2020 17:35:40

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '20 Oct 2020 11:59'	(b) (4), (b) (6) System	17 Oct 2020 17:35:40

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '20 Oct 2020 12:00'	(b) (4), (b) (6) System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '21 Oct 2020 11:59'	(b) (4), (b) (6) System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '21 Oct 2020 12:00'	(b) (4), (b) (6) System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '22 Oct 2020 11:59'	(b) (4), (b) (6) System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered '22 Oct 2020 12:00'	(b) (4), (b) (6) System	22 Oct 2020 16:58:43
	System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '22 Oct 2020 12:00'	(b) (4), (b) (6) System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '23 Oct 2020 11:59'	(b) (4), (b) (6) System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '23 Oct 2020 12:00'	(b) (4), (b) (6) System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '24 Oct 2020 11:59'	(b) (4), (b) (6) System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '24 Oct 2020 12:00'	(b) (4), (b) (6) System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '25 Oct 2020 11:59'	(b) (4), (b) (6) System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered '25 Oct 2020 15:25'	(b) (4), (b) (6) System	25 Oct 2020 20:23:25
	System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '25 Oct 2020 12:00'	(b) (4), (b) (6) System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '26 Oct 2020 11:59'	(b) (4), (b) (6) System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '26 Oct 2020 12:00'	(b) (4), (b) (6) System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '27 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '27 Oct 2020 12:00'	(b) (4), (b) (6) System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '28 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '28 Oct 2020 12:00'	(b) (4), (b) (6) System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '29 Oct 2020 11:59'	(b) (4), (b) (6) System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '29 Oct 2020 12:00'	(b) (4), (b) (6) System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '30 Oct 2020 11:59'	(b) (4), (b) (6) System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) System	30 Oct 2020 19:01:52
	System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '30 Oct 2020 12:00'	(b) (4), (b) (6) System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '31 Oct 2020 11:59'	(b) (4), (b) (6) System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '31 Oct 2020 12:00'	(b) (4), (b) (6) System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '01 Nov 2020 11:59'	(b) (4), (b) (6) System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered 'None (0)'	(b) (4), (b) (6) System	01 Nov 2020 22:29:34
	System	01 Nov 2020 22:29:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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' User entered '01 Nov 2020 16:31'	(b) (4), (b) (6) System	01 Nov 2020 22:29:34
	System	01 Nov 2020 22:29:34

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '01 Nov 2020 12:00'	(b) (4), (b) (6) System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Nov 2020 11:59'	(b) (4), (b) (6) System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '09 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 19:10:26

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	08 Oct 2020 21:16:26

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 22:25:14

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	10 Oct 2020 19:02:39

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	11 Oct 2020 19:22:05

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Oct 2020 18:18:41

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	12 Oct 2020 16:58:51

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 22:37:27

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '16 Oct 2020 12:00'	(b) (4), (b) (6) System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Oct 2020 11:59'	(b) (4), (b) (6) System	14 Oct 2020 18:18:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '17 Oct 2020 12:00'	(b) (4), (b) (6) System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Oct 2020 11:59'	(b) (4), (b) (6) System	15 Oct 2020 16:59:17

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '18 Oct 2020 12:00'	(b) (4), (b) (6) System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '19 Oct 2020 11:59'	(b) (4), (b) (6) System	16 Oct 2020 17:04:53

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	
	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '20 Oct 2020 12:00'	(b) (4), (b) (6) System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '21 Oct 2020 11:59'	(b) (4), (b) (6) System	18 Oct 2020 17:00:08

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) System	21 Oct 2020 18:19:55
User entered '21 Oct 2020 13:21'	System	21 Oct 2020 18:19:55

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '21 Oct 2020 12:00'	(b) (4), (b) (6) System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '22 Oct 2020 11:59'	(b) (4), (b) (6) System	19 Oct 2020 18:22:56

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '22 Oct 2020 12:00'	(b) (4), (b) (6) System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '23 Oct 2020 11:59'	(b) (4), (b) (6) System	20 Oct 2020 18:30:31

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '23 Oct 2020 12:00'	(b) (4), (b) (6) System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '24 Oct 2020 11:59'	(b) (4), (b) (6) System	21 Oct 2020 18:19:49

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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-a621-75c4fccec70b'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '24 Oct 2020 12:00'	(b) (4), (b) (6) System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '25 Oct 2020 11:59'	(b) (4), (b) (6) System	22 Oct 2020 16:58:43

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '25 Oct 2020 12:00'	(b) (4), (b) (6) System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '26 Oct 2020 11:59'	(b) (4), (b) (6) System	23 Oct 2020 16:59:04

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 22:14:41

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '26 Oct 2020 12:00'	(b) (4), (b) (6) System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '27 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Oct 2020 17:22:42

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '27 Oct 2020 12:00'	(b) (4), (b) (6) System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '28 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Oct 2020 20:23:25

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '28 Oct 2020 12:00'	(b) (4), (b) (6) System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '29 Oct 2020 11:59'	(b) (4), (b) (6) System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '29 Oct 2020 12:00'	(b) (4), (b) (6) System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '30 Oct 2020 11:59'	(b) (4), (b) (6) System	27 Oct 2020 19:49:38

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '30 Oct 2020 12:00'	(b) (4), (b) (6) System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '31 Oct 2020 11:59'	(b) (4), (b) (6) System	29 Oct 2020 13:43:45

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	31 Oct 2020 21:08:57
User entered '31 Oct 2020 16:10'	System	31 Oct 2020 21:08:57

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '31 Oct 2020 12:00'	(b) (4), (b) (6) System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '01 Nov 2020 11:59'	(b) (4), (b) (6) System	29 Oct 2020 17:03:34

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6)	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: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '01 Nov 2020 12:00'	(b) (4), (b) (6) System	30 Oct 2020 19:01:52

US3492064

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
User entered '02 Nov 2020 11:59'	(b) (4), (b) (6) System	30 Oct 2020 19:01:52

US3492064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	13 Oct 2020 16:51:04

US3492064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '12 Oct 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	13 Oct 2020 16:51:04

US3492064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	13 Oct 2020 16:51:04

US3492064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	13 Oct 2020 16:51:04
	(b) (4)	

US3492064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:00:34

US3492064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'I'	(b) (4), (b) (6) System	19 Oct 2020 15:00:34

US3492064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:00:52

US3492064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '16 Oct 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:00:52

US3492064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:00:52

US3492064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	19 Oct 2020 15:00:52
	(b) (4)	

US3492064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	19 Oct 2020 18:46:42
	(b) (4)	

US3492064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'I'	(b) (4), (b) (6) System	19 Oct 2020 18:46:42

US3492064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Nusirat Williams (b) (4)	26 Oct 2020 15:42:17

US3492064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '23 Oct 2020'	(b) (4) Nusirat Williams (b) (4)	26 Oct 2020 15:42:17

US3492064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nusirat Williams (b) (4)	26 Oct 2020 15:42:17

US3492064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	Nusirat Williams (b) (4)	26 Oct 2020 15:42:21
	(b) (4)	

US3492064

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'I'	(b) (4), (b) (6) System	26 Oct 2020 15:42:21

US3492064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	25 Nov 2020 21:05:23
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	25 Nov 2020 21:05:23
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4)	25 Nov 2020 21:05:23
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'VISIT3'	(b) (4), (b) (6) System	27 Oct 2020 14:34:28

US3492064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered '1'	(b) (4), (b) (6) System	27 Oct 2020 14:34:34

US3492064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) 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: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
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'	(b) (4), (b) (6) System	18 Nov 2020 09:46:00
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: 10 Jun 2021 07:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:14:41
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[Have you been exposed to someone with 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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2020-11-29T09:20:46', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'bda2ef33-9857-41b1-96cc-bee82635b804'	System	29 Nov 2020 15:18:43
User entered 'No (N)'	System	29 Nov 2020 15:18:43

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2020-11-29T09:20:50', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'bda2ef33-9857-41b1-96cc-bee82635b804'	System	29 Nov 2020 15:18:43
User entered 'No (N)'	System	29 Nov 2020 15:18:43

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-11-29T09:20:53', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'bda2ef33-9857-41b1-96cc-bee82635b804'	System	29 Nov 2020 15:18:43
User entered '29 Nov 2020 09:20:53'	System	29 Nov 2020 15:18:43

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2020-12-06T09:44:44', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f1284d4e-26ac-4bf0-9c18-24e455ef1dc9'	System	06 Dec 2020 15:42:43
User entered 'No (N)'	System	06 Dec 2020 15:42:43

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Have you been exposed to someone with 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: '2020-12-06T09:44:49', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f1284d4e-26ac-4bf0-9c18-24e455ef1dc9'	System	06 Dec 2020 15:42:43
User entered 'No (N)'	System	06 Dec 2020 15:42:43

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-12-06T09:44:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f1284d4e-26ac-4bf0-9c18-24e455ef1dc9'	System	06 Dec 2020 15:42:43
User entered '06 Dec 2020 09:44:55'	System	06 Dec 2020 15:42:43

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2020-12-17T13:10:25', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '944506c0-4662-4848-9d9d-e92f9653396a'	System	17 Dec 2020 19:08:07
User entered 'No (N)'	System	17 Dec 2020 19:08:07

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Have you been exposed to someone with 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: '2020-12-17T13:10:27', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '944506c0-4662-4848-9d9d-e92f9653396a'	System	17 Dec 2020 19:08:07
User entered 'No (N)'	System	17 Dec 2020 19:08:07

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-12-17T13:10:32', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '944506c0-4662-4848-9d9d-e92f9653396a' User entered '17 Dec 2020 13:10:32'	System	17 Dec 2020 19:08:07
	System	17 Dec 2020 19:08:07

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2020-12-20T08:49:12', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '09ac57f1-46ce-472e-b9cf-ceec12af4a8c'	System	20 Dec 2020 14:47:01
User entered 'No (N)'	System	20 Dec 2020 14:47:01

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Have you been exposed to someone with 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: '2020-12-20T08:49:22', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '09ac57f1-46ce-472e-b9cf-ceec12af4a8c'	System	20 Dec 2020 14:47:01
User entered 'No (N)'	System	20 Dec 2020 14:47:01

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-12-20T08:49:27', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '09ac57f1-46ce-472e-b9cf-ceec12af4a8c'	System	20 Dec 2020 14:47:01
User entered '20 Dec 2020 08:49:27'	System	20 Dec 2020 14:47:01

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2020-12-27T02:23:16', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a70b4f9e-1044-4a40-a877-d6307133e303'	System	27 Dec 2020 08:20:49
User entered 'No (N)'	System	27 Dec 2020 08:20:49

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2020-12-27T02:23:20', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a70b4f9e-1044-4a40-a877-d6307133e303'	System	27 Dec 2020 08:20:49
User entered 'No (N)'	System	27 Dec 2020 08:20:49

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2020-12-27T02:23:24', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a70b4f9e-1044-4a40-a877-d6307133e303'	System	27 Dec 2020 08:20:49
User entered '27 Dec 2020 02:23:24'	System	27 Dec 2020 08:20:49

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-01-05T15:37:16', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b7c59579-d156-438c-8372-5ee01ff73e49'	System	05 Jan 2021 21:34:45
User entered 'No (N)'	System	05 Jan 2021 21:34:45

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-01-05T15:37:19', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b7c59579-d156-438c-8372-5ee01ff73e49'	System	05 Jan 2021 21:34:45
User entered 'No (N)'	System	05 Jan 2021 21:34:45

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-05T15:37:25', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'b7c59579-d156-438c-8372-5ee01ff73e49'	System	05 Jan 2021 21:34:45
User entered '05 Jan 2021 15:37:25'	System	05 Jan 2021 21:34:45

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-01-14T16:30:48', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '2f1ef547-1287-4f88-8b1b-493e0e851893'	System	14 Jan 2021 22:28:10
User entered 'No (N)'	System	14 Jan 2021 22:28:10

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-01-14T16:30:52', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '2f1ef547-1287-4f88-8b1b-493e0e851893'	System	14 Jan 2021 22:28:10
User entered 'No (N)'	System	14 Jan 2021 22:28:10

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-14T16:30:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '2f1ef547-1287-4f88-8b1b-493e0e851893'	System	14 Jan 2021 22:28:10
User entered '14 Jan 2021 16:30:55'	System	14 Jan 2021 22:28:10

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-01-17T05:16:53', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f47bb86d-fff3-43c8-bbae-db9b2013dc28'	System	17 Jan 2021 11:14:33
User entered 'Yes (Y)'	System	17 Jan 2021 11:14:33

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-01-17T05:16:57', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f47bb86d-fff3-43c8-bbae-db9b2013dc28'	System	17 Jan 2021 11:14:33
User entered 'No (N)'	System	17 Jan 2021 11:14:33

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: '2021-01-17T05:17:05', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f47bb86d-fff3-43c8-bbae-db9b2013dc28'	System	17 Jan 2021 11:14:33
User entered 'No (N)'	System	17 Jan 2021 11:14:33

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: '2021-01-17T05:17:09', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f47bb86d-fff3-43c8-bbae-db9b2013dc28'	System	17 Jan 2021 11:14:33
User entered 'No (N)'	System	17 Jan 2021 11:14:33

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-17T05:17:21', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'f47bb86d-fff3-43c8-bbae-db9b2013dc28' User entered '17 Jan 2021 05:17:21'	System	17 Jan 2021 11:14:33
	System	17 Jan 2021 11:14:33

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-01-26T15:25:28', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered 'Yes (Y)'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-01-26T15:25:53', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered 'Yes (Y)'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:05', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: '2021-01-26T15:26:11', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered 'Yes (Y)'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '1'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:26:58', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '0'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:27:08', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: '2021-01-26T15:27:14', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered 'No (N)'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-26T15:27:47', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '0457435d-9d31-45c5-8735-3035cea665c4'	System	26 Jan 2021 21:59:18
User entered '26 Jan 2021 15:27:47'	System	26 Jan 2021 21:59:18

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-01-31T12:34:43', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9a0d663f-7c17-45b9-b50d-5dce8bdf5364'	System	31 Jan 2021 18:33:10
User entered 'Yes (Y)'	System	31 Jan 2021 18:33:10

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-01-31T12:34:55', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9a0d663f-7c17-45b9-b50d-5dce8bdf5364'	System	31 Jan 2021 18:33:10
User entered 'No (N)'	System	31 Jan 2021 18:33:10

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: '2021-01-31T12:35:51', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9a0d663f-7c17-45b9-b50d-5dce8bdf5364'	System	31 Jan 2021 18:33:10
User entered 'No (N)'	System	31 Jan 2021 18:33:10

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: '2021-01-31T12:35:57', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9a0d663f-7c17-45b9-b50d-5dce8bdf5364'	System	31 Jan 2021 18:33:10
User entered 'No (N)'	System	31 Jan 2021 18:33:10

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-01-31T12:36:04', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9a0d663f-7c17-45b9-b50d-5dce8bdf5364' User entered '31 Jan 2021 12:36:04'	System	31 Jan 2021 18:33:10
	System	31 Jan 2021 18:33:10

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-02-09T06:44:25', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '657980e9-3dc4-4f4d-908f-0034f499c67a'	System	09 Feb 2021 12:41:30
User entered 'No (N)'	System	09 Feb 2021 12:41:30

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-02-09T06:44:30', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '657980e9-3dc4-4f4d-908f-0034f499c67a'	System	09 Feb 2021 12:41:30
User entered 'No (N)'	System	09 Feb 2021 12:41:30

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-02-09T06:44:34', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '657980e9-3dc4-4f4d-908f-0034f499c67a'	System	09 Feb 2021 12:41:30
User entered '09 Feb 2021 06:44:34'	System	09 Feb 2021 12:41:30

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-02-18T23:00:51', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'feafb26e-4d85-4495-830b-26c1bd93495b'	System	19 Feb 2021 04:57:58
User entered 'No (N)'	System	19 Feb 2021 04:57:58

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-02-18T23:00:59', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'feafb26e-4d85-4495-830b-26c1bd93495b'	System	19 Feb 2021 04:57:58
User entered 'No (N)'	System	19 Feb 2021 04:57:58

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-02-18T23:01:08', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'feafb26e-4d85-4495-830b-26c1bd93495b' User entered '18 Feb 2021 23:01:08'	System	19 Feb 2021 04:57:58
	System	19 Feb 2021 04:57:58

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-02-22T04:06:27', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '4a21ed81-2b81-4374-ae16-5c05c74921c1'	System	22 Feb 2021 10:03:26
User entered 'No (N)'	System	22 Feb 2021 10:03:26

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-02-22T04:06:31', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '4a21ed81-2b81-4374-ae16-5c05c74921c1'	System	22 Feb 2021 10:03:26
User entered 'No (N)'	System	22 Feb 2021 10:03:26

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-02-22T04:06:36', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '4a21ed81-2b81-4374-ae16-5c05c74921c1'	System	22 Feb 2021 10:03:26
User entered '22 Feb 2021 04:06:36'	System	22 Feb 2021 10:03:26

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-02-28T05:15:34-06:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9a1a2786-55d2-403b-8030-d774a151f379'	System	28 Feb 2021 11:12:21
User entered 'No (N)'	System	28 Feb 2021 11:12:21

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-02-28T05:15:38-06:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9a1a2786-55d2-403b-8030-d774a151f379'	System	28 Feb 2021 11:12:21
User entered 'No (N)'	System	28 Feb 2021 11:12:21

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-02-28T05:15:41-06:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '9a1a2786-55d2-403b-8030-d774a151f379'	System	28 Feb 2021 11:12:21
User entered '28 Feb 2021 05:15:41'	System	28 Feb 2021 11:12:21

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-03-07T18:40:31-06:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '74ab7e43-a878-4e2d-96bc-920b9844f4df'	System	08 Mar 2021 00:37:14
User entered 'No (N)'	System	08 Mar 2021 00:37:14

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-03-07T18:40:33-06:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '74ab7e43-a878-4e2d-96bc-920b9844f4df'	System	08 Mar 2021 00:37:14
User entered 'No (N)'	System	08 Mar 2021 00:37:14

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-03-07T18:40:38-06:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '74ab7e43-a878-4e2d-96bc-920b9844f4df' User entered '07 Mar 2021 18:40:38'	System	08 Mar 2021 00:37:14
	System	08 Mar 2021 00:37:14

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-03-14T08:33:20-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '791a7e19-331b-425c-ba53-b546ecaa4964'	System	14 Mar 2021 13:30:06
User entered 'No (N)'	System	14 Mar 2021 13:30:06

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Have you been exposed to someone with 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: '2021-03-14T08:33:24-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '791a7e19-331b-425c-ba53-b546ecaa4964'	System	14 Mar 2021 13:30:06
User entered 'No (N)'	System	14 Mar 2021 13:30:06

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-03-14T08:33:28-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '791a7e19-331b-425c-ba53-b546ecaa4964' User entered '14 Mar 2021 08:33:28'	System	14 Mar 2021 13:30:06
	System	14 Mar 2021 13:30:06

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: '2021-04-05T01:35:37-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '57079a85-c5cc-4de1-b431-2dcabcceb4a6'	System	05 Apr 2021 06:32:06
User entered 'No (N)'	System	05 Apr 2021 06:32:06

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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: '2021-04-05T01:35:44-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '57079a85-c5cc-4de1-b431-2dcabcceb4a6'	System	05 Apr 2021 06:32:06
User entered 'No (N)'	System	05 Apr 2021 06:32:06

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-04-05T01:35:48-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '57079a85-c5cc-4de1-b431-2dcabcceb4a6'	System	05 Apr 2021 06:32:06
User entered '05 Apr 2021 01:35:48'	System	05 Apr 2021 06:32:06

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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 (d4e2c0726b3bb520)', Time: '2021-04-21T09:49:49-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5b7bf273-3934-41d6-98ab-ddb392a4bc47'	System	21 Apr 2021 14:50:11
User entered 'No (N)'	System	21 Apr 2021 14:50:11

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (d4e2c0726b3bb520)', Time: '2021-04-21T09:49:53-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5b7bf273-3934-41d6-98ab-ddb392a4bc47'	System	21 Apr 2021 14:50:11
User entered 'No (N)'	System	21 Apr 2021 14:50:11

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d4e2c0726b3bb520)', Time: '2021-04-21T09:50:01-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: '5b7bf273-3934-41d6-98ab-ddb392a4bc47'	System	21 Apr 2021 14:50:11
User entered '21 Apr 2021 09:50:01'	System	21 Apr 2021 14:50:11

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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 (d4e2c0726b3bb520)', Time: '2021-04-28T08:58:06-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c94fd45f-f431-40d8-92f6-548d32a2f2e0'	System	29 Apr 2021 01:15:09
User entered 'Yes (Y)'	System	29 Apr 2021 01:15:09

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

Have you been exposed to someone with 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 (d4e2c0726b3bb520)', Time: '2021-04-28T08:58:11-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c94fd45f-f431-40d8-92f6-548d32a2f2e0'	System	29 Apr 2021 01:15:09
User entered 'No (N)'	System	29 Apr 2021 01:15:09

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (d4e2c0726b3bb520)', Time: '2021-04-28T08:58:18-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c94fd45f-f431-40d8-92f6-548d32a2f2e0'	System	29 Apr 2021 01:15:09
User entered 'No (N)'	System	29 Apr 2021 01:15:09

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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 (d4e2c0726b3bb520)', Time: '2021-04-28T08:58:59-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c94fd45f-f431-40d8-92f6-548d32a2f2e0' User entered 'No (N)'	System	29 Apr 2021 01:15:09
	System	29 Apr 2021 01:15:09

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d4e2c0726b3bb520)', Time: '2021-04-28T08:59:03-05:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'c94fd45f-f431-40d8-92f6-548d32a2f2e0'	System	29 Apr 2021 01:15:09
User entered '28 Apr 2021 08:59:03'	System	29 Apr 2021 01:15:09

US3492064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:55:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:14:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-02-28T05:15:48-06:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a2977551-4f58-400d-8353-b36640dde2a6'	System	28 Feb 2021 11:12:34
User entered 'No (N)'	System	28 Feb 2021 11:12:34

US3492064

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:55:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:14:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0dea248b0b02d5d7)', Time: '2021-02-28T05:15:54-06:00', User OID: 'PatientReportedOutcome (US3492064)', ODM File OID: 'a2977551-4f58-400d-8353-b36640dde2a6' User entered '28 Feb 2021 05:15:54'	System	28 Feb 2021 11:12:34
	System	28 Feb 2021 11:12:34

US3492064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:18:48

US3492064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '24 Nov 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:18:48

US3492064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:18:48

US3492064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Lorna Sanchez McCann	25 Nov 2020 16:18:48
	(b) (4)	

US3492064

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:18:53

US3492064

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:43:12
User entered 'I'	(b) (4), (b) (6) System	25 Nov 2020 16:18:53

US3492064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	29 Dec 2020 20:00:27

US3492064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '29 Dec 2020'	Nia Moragne-O'Neal	29 Dec 2020 20:00:27

US3492064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	29 Dec 2020 20:00:27

US3492064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	Nia Moragne-O'Neal (b) (4)	29 Dec 2020 20:00:27

US3492064

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 20:00:31

US3492064

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User entered 'I'	(b) (4), (b) (6) System	29 Dec 2020 20:00:31

US3492064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	Ian Feather (b) (4)	28 Jan 2021 16:41:48
	(b) (4)	

US3492064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '28 Jan 2021'	(b) (4) Ian Feather (b) (4)	28 Jan 2021 16:41:48

US3492064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ian Feather (b) (4)	28 Jan 2021 16:41:48

US3492064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	(b) (4) Ian Feather (b) (4)	28 Jan 2021 16:41:48
	(b) (4)	

US3492064

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	Ian Feather (b) (4)	28 Jan 2021 16:41:53
	(b) (4)	

US3492064

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User entered 'I'	(b) (4), (b) (6) System	28 Jan 2021 16:41:53

US3492064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
	(b) (4)	
User entered 'Yes (Y)'	Nia Moragne-O'Neal	26 Feb 2021 20:25:48
	(b) (4)	

US3492064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '26 Feb 2021'	(b) (4) Nia Moragne-O'Neal (b) (4)	26 Feb 2021 20:25:48

US3492064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	26 Feb 2021 20:25:48

US3492064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	26 Feb 2021 20:25:48

US3492064

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	26 Feb 2021 20:25:51

US3492064

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:24:15
User entered 'I'	(b) (4), (b) (6) System	26 Feb 2021 20:25:51

US3492064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 are both dated 17 Mar 2021. However, the data on the Vital signs forms at one visit is recorded and the other visit is blank. Please reconcile. Thank you! ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:15:45
Query 'Per CDM: Visit 4 Day 209 and OL-D57 are both dated 17 Mar 2021. However, the data on the Vital signs forms at one visit is recorded and the other visit is blank. Please reconcile. Thank you! ' answered with 'entered' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	30 Mar 2021 17:31:38
User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 are both dated 17 Mar 2021. However, the data on the Vital signs forms at one visit is recorded and the other visit is blank. Please reconcile. Thank you! ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:18:48
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 15:13:39

US3492064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
	(b) (4)	
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 15:13:39

US3492064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Mar 2021 15:13:39

US3492064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User entered 'VISIT4'	System	17 Mar 2021 15:13:39

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	30 Mar 2021 17:32:33
	(b) (4)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '17 Mar 2021'	Marla Schwarber (b) (4)	30 Mar 2021 17:32:33
	(b) (4)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '10:19'	Marla Schwarber (b) (4)	30 Mar 2021 17:32:33
	(b) (4)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User entered '17 Mar 2021 10:19'	System	30 Mar 2021 17:32:33

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '98.2' F	Marla Schwarber (b) (4)	30 Mar 2021 17:32:33
	(b) (4)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'Other (Other)'	Marla Schwarber (b) (4)	30 Mar 2021 17:32:33
	(b) (4)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'tympanic'	Marla Schwarber (b) (4)	30 Mar 2021 17:32:33
	(b) (4)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '82'	Marla Schwarber (b) (4)	30 Mar 2021 17:32:33
	(b) (4)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User entered 'bpm'	System	30 Mar 2021 17:32:33

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '14'	Marla Schwarber (b) (4)	30 Mar 2021 17:32:33
	(b) (4)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User entered 'breaths/min'	System	30 Mar 2021 17:32:33

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '130'	Marla Schwarber (b) (4)	30 Mar 2021 17:32:33
	(b) (4)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User entered 'mmHg'	System	30 Mar 2021 17:32:33

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '77'	Marla Schwarber (b) (4)	30 Mar 2021 17:32:33
	(b) (4)	

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User entered 'mmHg'	System	30 Mar 2021 17:32:33

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33

US3492064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33

US3492064

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 15:38:02

US3492064

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
	(b) (4)	
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 15:38:02

US3492064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 15:38:11

US3492064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
	(b) (4)	
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 15:38:11

US3492064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
	(b) (4)	
User entered '10:20'	(b) (4), (b) (6)	17 Mar 2021 15:38:11

US3492064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User entered '17 Mar 2021 10:20'	System	17 Mar 2021 15:38:11

US3492064

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 15:13:46

US3492064

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:47:33
User entered '1'	System	17 Mar 2021 15:13:46

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:55:38

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:32:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '02 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	19 Nov 2020 20:14:46

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:55:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:32:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:15:10
User entered '12:00' reason for change: Data Entry Error	System	19 Nov 2020 20:15:10
User opened query 'Data is required. Please complete.' (Site from System).	Andrea Wendrow (b) (4)	19 Nov 2020 20:15:10
User entered empty.	(b) (4)	
	System	19 Nov 2020 20:14:46
	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: 10 Jun 2021 07:55:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:32:03
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: 10 Jun 2021 07:55:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:32:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Safety Call (Safety Call)'	(b) (4) Andrea Wendrow (b) (4)	19 Nov 2020 20:14:46

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:55:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:32:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Nov 2020 20:14:46

US3492064

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 07:55:38

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:32:11
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'No (N)'	Diana Bahena (b) (4)	16 Mar 2021 16:08:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 19:38:27

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 19:38:27

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:38:27

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	14 Jan 2021 19:38:27

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '0' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:38:04

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:38:04

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 14:08:44
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 14:08:44
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '1'	(b) (4), (b) (6) System	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'I'	(b) (4), (b) (6) System	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User entered empty.	System	14 Jan 2021 21:26:03
DataPoint set to visible.	System	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User entered empty.	System	14 Jan 2021 21:26:03
DataPoint set to visible.	System	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '13:47'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '14 Jan 2021 13:47'	(b) (4), (b) (6) System	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '98.7' F	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'not specified'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '70'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'bpm'	(b) (4), (b) (6) System	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '118'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mmHg'	(b) (4), (b) (6) System	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '72'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mmHg'	(b) (4), (b) (6) System	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User entered empty.	System	14 Jan 2021 21:26:03
DataPoint set to visible.	System	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '15:16'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '14 Jan 2021 15:16'	(b) (4), (b) (6) System	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '98.7' F	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Other (Other)'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'not specified'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '65'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'bpm'	(b) (4), (b) (6) System	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '128'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mmHg'	(b) (4), (b) (6) System	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '79'	(b) (4), (b) (6)	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mmHg'	(b) (4), (b) (6) System	14 Jan 2021 21:26:03

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Jan 2021 21:24:19

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:24:19

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:26:24

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 21:26:24

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:26:24

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User entered 'mRNA-1273'	System	14 Jan 2021 21:26:24
DataPoint set to visible.	System	14 Jan 2021 20:13:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 21:26:24

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '14:45'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:26:24

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '14 Jan 2021 14:45'	(b) (4), (b) (6) System	14 Jan 2021 21:26:24

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:26:24

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'ONCE'	(b) (4), (b) (6) System	14 Jan 2021 21:26:24

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	14 Jan 2021 21:26:24

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 21:24:38

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 21:24:38

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '13:51'	(b) (4), (b) (6)	14 Jan 2021 21:24:38

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '14 Jan 2021 13:51'	(b) (4), (b) (6) System	14 Jan 2021 21:24:38

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:24:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:55:38

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 21:24:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '14:00'	(b) (4), (b) (6)	14 Jan 2021 21:24:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:55:38

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '14 Jan 2021 14:00'	(b) (4), (b) (6) System	14 Jan 2021 21:24:48

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 20:13:58

US3492064

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'I'	(b) (4), (b) (6) System	14 Jan 2021 20:13:58

US3492064

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Jan 2021 18:00:57

US3492064

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '21 Jan 2021'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Jan 2021 18:00:57

US3492064

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Jan 2021 18:00:57

US3492064

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Jan 2021 18:00:57

US3492064

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Jan 2021 18:01:01

US3492064

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User entered 'I'	(b) (4), (b) (6) System	21 Jan 2021 18:01:01

US3492064

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
	(b) (4), (b) (6)	
User entered '1'	System	21 Jan 2021 18:01:01
DataPoint set to visible.	System	21 Jan 2021 18:01:01

US3492064

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:39:18

US3492064

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:39:18

US3492064

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:39:18

US3492064

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'OLD29'	(b) (4), (b) (6) System	19 Feb 2021 16:39:18

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '10:20'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '19 Feb 2021 10:20'	(b) (4), (b) (6) System	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'not specified'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '70'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'bpm'	(b) (4), (b) (6) System	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '14'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'breaths/min'	(b) (4), (b) (6) System	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '136'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '78'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '11:20'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '19 Feb 2021 11:20'	(b) (4), (b) (6) System	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'ear'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '70'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'bpm'	(b) (4), (b) (6) System	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '14'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'breaths/min'	(b) (4), (b) (6) System	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '129'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '84'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 19:52:41

US3492064

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:39:26

US3492064

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:39:26

US3492064

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:59:16

US3492064

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:59:16

US3492064

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:59:16

US3492064

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mRNA-1273'	(b) (4), (b) (6)	19 Feb 2021 16:59:16
DataPoint set to visible.	System	21 Jan 2021 18:01:01

US3492064

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:59:16

US3492064

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '10:50'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:59:16

US3492064

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '19 Feb 2021 10:50'	(b) (4), (b) (6) System	19 Feb 2021 16:59:16

US3492064

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:59:16

US3492064

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'ONCE'	(b) (4), (b) (6) System	19 Feb 2021 16:59:16

US3492064

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	19 Feb 2021 16:59:16

US3492064

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:59:20

US3492064

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'I'	(b) (4), (b) (6) System	19 Feb 2021 16:59:20

US3492064

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	26 Feb 2021 19:23:14

US3492064

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '26 Feb 2021'	(b) (4) Nia Moragne-O'Neal (b) (4)	26 Feb 2021 19:23:14

US3492064

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	26 Feb 2021 19:23:14

US3492064

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	26 Feb 2021 19:23:14

US3492064

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	26 Feb 2021 19:23:23

US3492064

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:10:39
User entered 'I'	(b) (4), (b) (6) System	26 Feb 2021 19:23:23

US3492064

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:14:00

US3492064

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:14:00

US3492064

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:14:00

US3492064

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'OLD57'	(b) (4), (b) (6) System	17 Mar 2021 15:14:00

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '10:19'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '17 Mar 2021 10:19'	(b) (4), (b) (6) System	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '82'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'bpm'	(b) (4), (b) (6) System	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '14'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '130'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mmHg'	(b) (4), (b) (6) System	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '77'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered 'mmHg'	(b) (4), (b) (6) System	17 Mar 2021 17:25:29

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:09:58

US3492064

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 11:09:58

US3492064

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:37:35

US3492064

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:37:35

US3492064

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:37:52

US3492064

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:37:52

US3492064

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Mar 2021 01:40:56
User entered '10:20'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:37:52

US3492064

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:09:58
User entered '17 Mar 2021 10:20'	(b) (4), (b) (6) System	17 Mar 2021 15:37:52

US3492064

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:55:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:55:06
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 2; end date: Day 16). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:55:12
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 2; end date: Day 16). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.'	(b) (4), (b) (6)	29 Mar 2021 20:55:57
answered with 'added to AE' (Site from DM).		
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 2; end date: Day 16). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:05:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:40:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Elena Llinas (b) (4) (b) (4)	18 Sep 2020 20:29:40
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:50:02

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
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, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (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)	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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
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
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query ' Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 10:03:04
Query ' Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 14:40:06
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 14:39:59
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Feb 2021 14:39:59
User opened query ' Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:48:35
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
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)	18 Sep 2020 20:32:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
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
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 17:39:49
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
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
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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)	25 Sep 2020 19:46:38
	(b) (4)	
User entered 'Yes (Y)'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
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)	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)	25 Sep 2020 19:46:38
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 20:32:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User entered empty.	System	18 Sep 2020 20:32:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

US3492064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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:	Elena Llinas (b) (4)	18 Sep 2020 21:04:10
Data Entry Error	(b) (4)	
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
	(b) (4)	

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'I'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	29 Oct 2020 18:13:27
Data Entry Error		
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)	18 Sep 2020 21:04:10
	(b) (4)	
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
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Elena Llinas (b) (4)	18 Sep 2020 20:32:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User entered '0'	System	18 Sep 2020 20:32:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:55:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25
User entered '0'	System	18 Sep 2020 20:32:07

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of JOINT ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 10:05:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 16:56:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 16:56:02
Data point term sent to Coder	System	11 Jan 2021 16:39:55
Query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of JOINT ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with '-----Corrected. thank you.-----' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 16:39:07
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 16:39:02
Coding entries removed.	(b) (4), (b) (6)	11 Jan 2021 16:39:02
User entered 'Generalized JOINT ACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 16:39:02
User opened query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of JOINT ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 02:25:34
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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Joint Aches'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:40:56
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 11:40:51
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'updated. changed to yes because "arthralgia (joint aches in several joints)" is listed in Table 5 as a solicited adverse reaction and this reaction has lasted more than 7 days post injection, outside of the reactogenicity period' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 14:22:11
Signature has been broken.	(b) (4), (b) (6)	24 Feb 2021 14:19:05
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Feb 2021 14:19:05
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:59:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Un-verified.	(b) (4) Ian Feather (b) (4)	28 Jan 2021 17:52:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Ian Feather (b) (4)	28 Jan 2021 17:52:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Yes (Y)'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES on 05SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 21:13:23
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES on 05SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'data entry error. date has been fixed' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 19:40:53
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 19:40:03
User entered '5 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 19:40:03
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom JOINT ACHES on 05SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 02:25:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '4 Sep 2020'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	26 Oct 2020 15:45:54

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Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 15:45:54

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:37:52
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'See narrative 28JAN2021' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	08 Feb 2021 18:30:16
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:20:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Ian Feather (b) (4) (b) (4)	28 Jan 2021 17:51:38
User entered 'No (N)' reason for change: New Information	Ian Feather (b) (4) (b) (4)	28 Jan 2021 17:50:01
User entered 'Yes (Y)' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:43:21
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:52:29
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'updated' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 22:17:04
DataPoint Un-verified.	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 22:15:56

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Marla Schwarber (b) (4)	30 Nov 2020 22:15:56
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 12:11:56
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

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty; reason for change Data Entry Error	Ian Feather (b) (4)	28 Jan 2021 17:51:38
	(b) (4)	
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	28 Jan 2021 17:50:24
User entered '29 Dec 2020' reason for change: New Information	Ian Feather (b) (4)	28 Jan 2021 17:50:24
	(b) (4)	
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	28 Jan 2021 17:50:01
User entered '29 Dec 2019' reason for change: New Information	Ian Feather (b) (4)	28 Jan 2021 17:50:01
	(b) (4)	
User entered empty; reason for change New Information	Nia Moragne-O'Neal	29 Dec 2020 19:43:21
	(b) (4)	
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	30 Nov 2020 22:16:49
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	30 Nov 2020 22:16:49
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	30 Nov 2020 22:15:56
DataPoint Un-verified.	Marla Schwarber (b) (4)	30 Nov 2020 22:15:56
	(b) (4)	
User entered '20 Sep 2020' reason for change: Per Query Resolution	Marla Schwarber (b) (4)	30 Nov 2020 22:15:56
	(b) (4)	
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
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 17:51:38
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Jan 2021 17:50:01
User entered empty; reason for change New Information	Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:43:21
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Nov 2020 22:16:49
DataPoint Un-verified.	Marla Schwarber (b) (4)	30 Nov 2020 22:16:49
	(b) (4)	
User entered '12:00' reason for change: New Information	Marla Schwarber (b) (4)	30 Nov 2020 22:16:49
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Nov 2020 22:15:56
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
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Dec 2020 19:43:21
User entered '20 Sep 2020 12:00'	System	30 Nov 2020 22:16:49
User entered empty.	System	26 Oct 2020 15:45:54

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	Ian Feather (b) (4)	28 Jan 2021 17:52:41
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ian Feather (b) (4)	28 Jan 2021 17:52:41
reason for change: Data Entry Error	(b) (4)	
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	Ian Feather (b) (4)	28 Jan 2021 17:52:41
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ian Feather (b) (4)	28 Jan 2021 17:52:41
reason for change: Data Entry Error	(b) (4)	
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'Per CDM: Action Taken with investigational Product = Not Applicable, however AE start date is prior to second dose of IP. Please review and update response as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 10:04:21
Query 'Per CDM: Action Taken with investigational Product = Not Applicable, however AE start date is prior to second dose of IP. Please review and update response as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 14:40:58
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 14:40:52
User opened query 'Per CDM: Action Taken with investigational Product = Not Applicable, however AE start date is prior to second dose of IP. Please review and update response as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 13:14:00
DataPoint Un-verified.	Ian Feather (b) (4)	28 Jan 2021 17:52:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Ian Feather (b) (4)	28 Jan 2021 17:52:41
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)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'I'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Ian Feather (b) (4)	28 Jan 2021 17:51:38
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Ian Feather (b) (4)	28 Jan 2021 17:50:01
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Nia Moragne-O'Neal	29 Dec 2020 19:43:21
	(b) (4)	
DataPoint Un-verified.	Marla Schwarber (b) (4)	30 Nov 2020 22:16:49
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Marla Schwarber (b) (4)	30 Nov 2020 22:16:49
	(b) (4)	
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered empty.	Nusirat Williams (b) (4) (b) (4)	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'PARTICIPANT REPORTS 28JAN2021 THAT while aches are still generalized, the focal point is now his right shoulder and the aches elsewhere are improving.' reason for change: Data Entry Error	Ian Feather (b) (4)	28 Jan 2021 18:07:15
	(b) (4)	
User entered empty; reason for change Data Entry Error	Ian Feather (b) (4)	28 Jan 2021 17:51:38
	(b) (4)	
User entered 'PARTICIPANT REPORTS 28JAN2021 THAT HE IS NOW ONLY EXPERIENCING A JOINT ACHE OF THE RIGHT SHOULDER, so new AE reflecting new, localized nature will be created.' reason for change: New Information	Ian Feather (b) (4)	28 Jan 2021 17:48:05
	(b) (4)	
DataPoint Un-verified.	Ian Feather (b) (4)	28 Jan 2021 16:41:29
	(b) (4)	
User entered 'Participant reports 28Jan2021 that he is now only experiencing a joint ache of the right shoulder.' reason for change: New Information	Ian Feather (b) (4)	28 Jan 2021 16:41:29
	(b) (4)	
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
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 15:45:54

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4)	
	(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	System	03 Nov 2020 20:32:17
'USA-US101-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	03 Nov 2020 20:32:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	Marla Schwarber (b) (4)	30 Nov 2020 22:04:52
	(b) (4)	
User entered '30 Oct 2020' reason for change: New Information	Marla Schwarber (b) (4)	30 Nov 2020 22:04:52
	(b) (4)	
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
	(b) (4)	
User entered '30 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: 10 Jun 2021 07:55:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 19:54:49
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
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) (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) (b) (4)	19 Nov 2020 23:00:42
User closed query 'End time is present for an AE that System did not start within 24 hours after dosing. Please remove the End time.' (Site from 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) (b) (4)	19 Nov 2020 23:00:16
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) (b) (4)	19 Nov 2020 22:59:28
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
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

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[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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
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).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 04:32:30
DataPoint Verified.	(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) (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 'I'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

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[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	Marla Schwarber (b) (4)	30 Nov 2020 22:04:19
	(b) (4)	
User entered '30 Oct 2020' reason for change: Per Query Resolution	Marla Schwarber (b) (4)	30 Nov 2020 22:04:19
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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) (b) (4)	19 Nov 2020 19:34:07
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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). 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).	System	19 Nov 2020 19:34:07
User entered 'Yes (Y)' reason for change: New Information	Marla Schwarber (b) (4) (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). User entered 'Unknown (UNK)'	System Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '11' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 19:34:07
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '1' reason for change: Per Query Resolution	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 19:34:07
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
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) (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) (b) (4)	19 Nov 2020 19:34:51
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Marla Schwarber (b) (4) (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) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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None

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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'	(b) (4) Andrea Wendrow (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:55:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:27:46
DataPoint Verified.	(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) (b) (4)	19 Nov 2020 20:47:31
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:40:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 19:34:07
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) (b) (4)	02 Nov 2020 23:48:15

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Form: Adverse Events (3)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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) (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).	System	19 Nov 2020 20:40:18
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'PV Query: Start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms, 30 Oct 2020. If not updating the start date, please clarify.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:23:12
User closed query 'PV Query: Please consider COVID positive as serious adverse event.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 18:23:10
Query 'PV Query: Please consider COVID positive as serious adverse event.' answered with 'COVID was asymptomatic and not the reason for admission; therefore, will not report as SAE.' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 22:07:57
Query 'PV Query: Start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms, 30 Oct 2020. If not updating the start date, please clarify.' answered with 'Start date updated' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 22:05:23
User opened query 'PV Query: Please consider COVID positive as serious adverse event.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 22:57:04
User opened query 'PV Query: Start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms, 30 Oct 2020. If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 22:56:55
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

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
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)	19 Nov 2020 22:53:53
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

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
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
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

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
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)	(b) (4) 02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[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)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Nov 2020 23:48:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[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: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Yes (Y)'	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: 10 Jun 2021 07:55:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
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) (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)

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '31 Oct 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

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Folder: Adverse Events

Form: Adverse Events (4)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

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Folder: Adverse Events

Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'I'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:39:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	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: 10 Jun 2021 07:55:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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) (b) (4)	19 Nov 2020 21:10:34

US3492064

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 21:10:34

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
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)	29 Mar 2021 20:55:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 20:55:11
	(b) (4)	
Data point term sent to Coder	System	29 Mar 2021 20:54:51
User entered 'general muscle aches'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
User closed query 'Per DM RQ: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 05:56:04
Query 'Per DM RQ: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:57:45
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Apr 2021 13:57:28
User opened query 'Per DM RQ: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:39:52
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:10:50
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' answered with 'Symptom lasted beyond Day 7.. Per FAQ v26.0_26Mar2021.pdf page 31 of 119 it is to be reported as an UNSOLICITED AE' (Site from DM).	Marla Schwarber (b) (4)	06 Apr 2021 17:53:35
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 15:30:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '03 Oct 2020'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 20:54:50
User entered '12:00' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Mar 2021 20:54:50
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 20:54:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:54:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User entered '03 Oct 2020 12:00'	System	29 Mar 2021 20:54:50
User entered empty.	System	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '17 Oct 2020'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 20:54:50
User entered '12:00' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Mar 2021 20:54:50
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 20:54:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User entered '17 Oct 2020 12:00'	System	29 Mar 2021 20:54:50
User entered empty.	System	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:22:53
	(b) (4)	
User entered 'reported in diary dose 2'	(b) (4), (b) (6)	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User entered '0'	System	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32
User entered '0'	System	29 Mar 2021 20:54:36

US3492064

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:41:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:55:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:55:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	Marla Schwarber (b) (4)	25 Nov 2020 20:22:43
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Marla Schwarber (b) (4)	25 Nov 2020 20:22:43
	(b) (4)	
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	Marla Schwarber (b) (4)	25 Nov 2020 20:22:43
	(b) (4)	
User entered '31 Oct 2020' reason for change: New Information	Marla Schwarber (b) (4)	25 Nov 2020 20:22:43
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4) (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: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User entered '1'	(b) (4), (b) (6) System	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User entered '1'	(b) (4), (b) (6) System	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:21:50
User entered '804 (804)'	(b) (4), (b) (6) System	08 Sep 2020 16:00:14

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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) (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 16:02:58
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: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:02:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: ERYTHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 18:49:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 18:49:55
Data point term sent to Coder	System	17 Dec 2020 15:38:41
Coding entries removed.	(b) (4), (b) (6)	17 Dec 2020 15:38:14
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	System	29 Oct 2020 15:58:10
Coding entries removed.	(b) (4), (b) (6)	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	System	08 Sep 2020 16:05:05
User entered 'erythromycin'	(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: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'Per DM CLR: Please be advised the RUNNY EYE ISSUE condition is still not recorded on the MH eCRF. Please review Con Med use, add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 09:12:27
Query 'Per DM CLR: Please be advised the RUNNY EYE ISSUE condition is still not recorded on the MH eCRF. Please review Con Med use, add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'runny eye issue is just from a corneal abrasion, a symptom of it' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 15:38:42
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 15:38:14
User entered 'RUNNY EYE ISSUE due to CORNEAL ABRASION' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 15:38:14
User opened query 'Per DM CLR: Please be advised the RUNNY EYE ISSUE condition is still not recorded on the MH eCRF. Please review Con Med use, add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:44:57
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

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
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.	(b) (4), (b) (6)	23 Oct 2020 08:53:26
' (Site from DM).		
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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
User entered 'I'	(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: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	Marla Schwarber (b) (4)	25 Nov 2020 20:23:46
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Marla Schwarber (b) (4)	25 Nov 2020 20:23:46
	(b) (4)	
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: 10 Jun 2021 07:55:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Un-verified.	(b) (4) Marla Schwarber (b) (4)	25 Nov 2020 20:23:46
User entered '31 Oct 2020' reason for change: New Information	(b) (4) Marla Schwarber (b) (4)	25 Nov 2020 20:23:46
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: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4), (b) (6)	
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: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:22:20
User entered empty.	(b) (4), (b) (6) System	08 Sep 2020 16:04:41

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'med history updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 06:58:30
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:12:33
User entered 'BPH'	(b) (4), (b) (6)	02 Dec 2020 06:35:48
	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

[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: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
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.	(b) (4) Coder Import (b) (4) (b) (4)	25 Nov 2020 22:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 22:19:32
Data point term sent to Coder DataPoint Un-verified.	System Marla Schwarber (b) (4)	25 Nov 2020 21:42:34 25 Nov 2020 21:41:39
Coding entries removed.	(b) (4) Marla Schwarber (b) (4)	25 Nov 2020 21:41:39
User entered 'CLOPIDogrel' reason for change: Data Entry Error DataPoint Verified.	(b) (4) Marla Schwarber (b) (4) (b) (4) (b) (4), (b) (6)	25 Nov 2020 21:41:39 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 User entered 'clopidogrel'	System Marla Schwarber (b) (4) (b) (4)	19 Nov 2020 20:28:34 19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4) 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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'ASCVD prophylaxis'	(b) (4) 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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '75'	(b) (4) 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: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'mg (mg)'	(b) (4) 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: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4)	19 Nov 2020 20:28:06
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	(b) (4) 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: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4)	19 Nov 2020 20:28:06
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4)	19 Nov 2020 20:28:06
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 18:57:08
	(b) (4), (b) (6)	
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:57:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4)	
User entered '31 Oct 2020'	Marla Schwarber (b) (4)	19 Nov 2020 20:28:06
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	Marla Schwarber (b) (4)	19 Nov 2020 20:28:06
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 18:57:08
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:57:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4)	
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	19 Nov 2020 20:28:06
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 18:57:08
	(b) (4), (b) (6)	
User entered '29 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 18:57:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4)	
User entered empty.	Marla Schwarber (b) (4)	19 Nov 2020 20:28:06
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4) 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: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
User entered '1'	(b) (4), (b) (6) System	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
User entered '1'	(b) (4), (b) (6) System	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:14
User entered '804 (804)'	(b) (4), (b) (6) System	19 Nov 2020 20:28:06

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4) 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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'thrombus prophylaxis'	(b) (4) 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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '5000'	(b) (4) 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: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Other (OTHER)'	(b) (4) 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: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'units'	Marla Schwarber (b) (4)	19 Nov 2020 20:31:27
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	(b) (4) 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: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4)	19 Nov 2020 20:31:27
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) 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: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	Marla Schwarber (b) (4)	19 Nov 2020 20:31:27
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '31 Oct 2020'	Marla Schwarber (b) (4)	19 Nov 2020 20:31:27
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	(b) (4) 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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	Marla Schwarber (b) (4)	19 Nov 2020 20:31:27
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '11 Nov 2020'	(b) (4) 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: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4) 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: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User entered '1'	(b) (4), (b) (6) System	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User entered '1'	(b) (4), (b) (6) System	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:19
User entered '804 (804)'	(b) (4), (b) (6) System	19 Nov 2020 20:31:27

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	(b) (4) 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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Prevent constipation'	(b) (4) 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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'g (g)'	(b) (4) 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: 10 Jun 2021 07:55:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	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: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	(b) (4) 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: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4) 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: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Oral (ORAL)'	(b) (4) 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: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '31 Oct 2020'	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: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '0'	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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4) 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: 10 Jun 2021 07:55:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '11 Nov 2020'	(b) (4) 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: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User entered '1'	(b) (4), (b) (6) System	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User entered '1'	(b) (4), (b) (6) System	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:24
User entered '804 (804)'	(b) (4), (b) (6) System	19 Nov 2020 20:33:58

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'Yes (Y)'	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: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'prevent constipation'	(b) (4) 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: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User closed query 'Per DM CLR: Please provide the actual dose rather than the number of tablets, as there are various dosages available for this medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 09:13:28
Query 'Per DM CLR: Please provide the actual dose rather than the number of tablets, as there are various dosages available for this medication. Please update as appropriate or provide clarification.' answered with '-----updated dosage. takes two 8.6mg tablets daily-----' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:25:33
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 19:24:41
User entered '17.2' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 19:24:41
User opened query 'Per DM CLR: Please provide the actual dose rather than the number of tablets, as there are various dosages available for this medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:46:32
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: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 19:24:41
	(b) (4), (b) (6)	
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 19:24:41
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
	(b) (4)	
User entered 'tablet (TABLET)'	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: 10 Jun 2021 07:55:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	(b) (4) 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: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'once daily (QD)'	(b) (4) 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: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	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: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered empty.	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: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '31 Oct 2020'	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: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
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: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4) 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: 10 Jun 2021 07:55:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered '11 Nov 2020'	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: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:56:04
User entered 'No (N)'	(b) (4) 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: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
User entered '1'	(b) (4), (b) (6) System	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
User entered '1'	(b) (4), (b) (6) System	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:56
User entered '804 (804)'	(b) (4), (b) (6) System	19 Nov 2020 20:35:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Response indicates that this medication was taken for CVA, however Indication is recorded as Hyperlipidemia. Please review and update Indication as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:09:58
Query 'Per CDM re-query: Response indicates that this medication was taken for CVA, however Indication is recorded as Hyperlipidemia. Please review and update Indication as appropriate or clarify.' answered with 'the dose was increased due to CVA but is still taken for hyperlipidemia; the conditions are related a stroke is due to high cholesterol, also know as hyperlipidemia' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 20:47:33
User opened query 'Per CDM re-query: Response indicates that this medication was taken for CVA, however Indication is recorded as Hyperlipidemia. Please review and update Indication as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:40:19
User closed query 'Per DM CLR: Was the dose of this medication increased from 40 mg to 80 mg because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for increased dose. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:40:19
Query 'Per DM CLR: Was the dose of this medication increased from 40 mg to 80 mg because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for increased dose. ' answered with 'CVA happened on october 30th and atorvastatin was increased on october 31st as a result of the stroke' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 20:07:46

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was the dose of this medication increased from 40 mg to 80 mg because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for increased dose. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:00:42
Query 'Missed - Per DM CLR: Was the dose of this medication increased from 40 mg to 80 mg because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for increased dose.	(b) (4), (b) (6)	23 Feb 2021 07:00:35
' canceled (Site from DM).		
User opened query 'Missed - Per DM CLR: Was the dose of this medication increased from 40 mg to 80 mg because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for increased dose.	(b) (4), (b) (6)	23 Feb 2021 07:00:33
' (Site from DM).		
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User coded data point as ATC:	(b) (4)	
CARDIOVASCULAR SYSTEM, ATC: LIPID	Coder Import (b) (4)	25 Nov 2020 20:27:37
MODIFYING AGENTS, ATC: LIPID MODIFYING	(b) (4)	
AGENTS, PLAIN, ATC: HMG COA REDUCTASE		
INHIBITORS, PRODUCT: ATORVASTATIN -		
version WHODrug-Global-B3\\202003.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	25 Nov 2020 20:27:37
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	25 Nov 2020 20:26:20
User entered 'atorvastatin'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'No (N)'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'hyperlipidemia'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '80'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'mg (mg)'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'once daily (QD)'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '31 Oct 2020'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '0'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered 'No (N)'	Marla Schwarber (b) (4)	25 Nov 2020 20:26:19
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 20:26:19

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 20:26:19

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 20:26:19

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 20:01:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 20:01:20
	(b) (4)	
Data point term sent to Coder	System	29 Dec 2020 19:45:20
User entered 'influenza vaccine'	Nia Moragne-O'Neal	29 Dec 2020 19:44:54
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'prevent influenza'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'unk'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Other (OTHER)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'unk'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'once (ONCE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '29 Oct 2020'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '29 Oct 2020'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User entered empty.	(b) (4), (b) (6) System	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User entered empty.	(b) (4), (b) (6) System	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:15
User entered empty.	(b) (4), (b) (6) System	29 Dec 2020 19:44:54

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 21:17:20
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 Dec 2020 21:17:20
Data point term sent to Coder	System	29 Dec 2020 19:46:23
User entered 'shingles shot'	Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'prevent shingles'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'unk'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Other (OTHER)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'unk'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'once (ONCE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Nia Moragne-O'Neal	29 Dec 2020 19:45:39
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
	(b) (4), (b) (6)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered empty.	Nia Moragne-O'Neal	29 Dec 2020 19:45:39
	(b) (4)	

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '29 Oct 2020'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '0'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '29 Oct 2020'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) Nia Moragne-O'Neal (b) (4)	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User entered empty.	(b) (4), (b) (6) System	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User entered empty.	(b) (4), (b) (6) System	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User entered empty.	(b) (4), (b) (6) System	29 Dec 2020 19:45:39

US3492064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:55:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'No (N)'	(b) (4) (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: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
Reviewed for Safety.	(b) (4)	
	(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: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '3'	(b) (4)	01 Dec 2020 18:23:50
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: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
Reviewed for Safety.	(b) (4)	
	(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: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '3'	System	01 Dec 2020 18:23:50
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: 10 Jun 2021 07:55:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 23:28:39
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:40:12
User entered 'I'	(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: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
Reviewed for Safety.	(b) (4)	
	(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: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '3'	System	01 Dec 2020 18:23:50
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: 10 Jun 2021 07:55:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '20/Nov/2020 18:29'	(b) (4) System	20 Nov 2020 23:29:04

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:55:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:23:36
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 23:29:04

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 07:55:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
Reviewed for Safety.	(b) (4)	
	(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: 10 Jun 2021 07:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 07:55:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 07:55:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
	(b) (4)	
User entered '3'	System	01 Dec 2020 18:23:50
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 (3)

Generated On: 10 Jun 2021 07:55:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered '01/Dec/2020 13:23'	(b) (4) System	01 Dec 2020 18:23:50

US3492064

Folder: SAE USA-US101-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:55:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:36:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:23:50