

US3462091 (Prod: Crisor, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:29:21

All time stamps listed in this document are displayed in GMT

US3462091

Form: Participant Creation

Generated On: 26 Nov 2020 09:29:21

[Participant ID](#)

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

US3462091

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:29:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:29:21

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

Condition	RIGHT EYE CATARACT
Start date (dd MMM yyyy)	UN (b) (6) 1953
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1953
Start Year (derived)	1953
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

Condition	LEFT EYE CATARACT
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION
Start date (dd MMM yyyy)	24 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	29 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

Condition	LEFT SHOULDER DAMAGE
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

Condition	BILATERAL KNEE DAMAGE
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

Condition	LOWER BACK RUPTURED DISCS
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

Condition	GALL BLADDER STONES
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:46 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:46
Height (<i>xxx.x</i>)	183 cm
Weight (<i>xxx.x</i>)	142.0 kg
BMI (<i>xxx.x</i>)	42.40198 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

PATIENT WORKS IN A CAR SHOP WITH TWO CO-WORKERS, . PATIENT HAS 3-4 CUSTOMERS PER WEEK AND WORKS 5 DAYS PER WEEK.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
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	True
Specify	PATIENT ATTEND CHURCH TWICE WEEKLY, WITH 100 OR MORE OTHER CHURCH MEMBERS.

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:21

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

What was the participant's randomization number? 185134

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:46
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 11:50
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

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.

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 AUG 2020

What was the treatment time? (00:00-23:59) 10:43 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 10:43

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	10 AUG 2020
Collection time (<i>00:00-23:59</i>)	10:31 (24 HR)
Collection date and time (derived)	10 AUG 2020 10:31

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:21

Collection date (<i>dd MMM yyyy</i>)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:34	10 AUG 2020 10:34
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp 10 AUG 2020 11:51

PC Open Date & Time 10 AUG 2020 11:03

PC Close Date & Time 10 AUG 2020 13:33

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °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	10 AUG 2020 17:04
PC Open Date & Time	10 AUG 2020 14:28
PC Close Date & Time	11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

11 AUG 2020 18:08

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

12 AUG 2020 18:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

97.3 °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

13 AUG 2020 17:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

97.2 °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

14 AUG 2020 20:15

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

97.9 °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

15 AUG 2020 18:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

16 AUG 2020 17:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

10 AUG 2020 11:52

PC Open Date & Time

10 AUG 2020 11:03

PC Close Date & Time

10 AUG 2020 13:33

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 17:05

PC Open Date & Time

10 AUG 2020 14:28

PC Close Date & Time

11 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 18:09

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 18:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

13 AUG 2020 17:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 20:15

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 18:32

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

16 AUG 2020 17:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 11:53
PC Open Date & Time	10 AUG 2020 11:03
PC Close Date & Time	10 AUG 2020 13:33

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 17:05
PC Open Date & Time	10 AUG 2020 14:28
PC Close Date & Time	11 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	12 AUG 2020 18:03
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	13 AUG 2020 17:03
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	14 AUG 2020 20:15
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	15 AUG 2020 18:32
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	16 AUG 2020 17:02
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3462091

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462091

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462091

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462091

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	10:23 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:23
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:42
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 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

US3462091

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

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.

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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)	8 SEP 2020
What was the treatment time? (00:00-23:59)	11:05 (24 HR)
Treatment Date and Time (derived)	8 SEP 2020 11:05
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

US3462091

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

08 SEP 2020

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

10:58 (24 HR)

Collection date and time (derived)

08 SEP 2020 10:58

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:21

Collection date (<i>dd MMM yyyy</i>)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:00	08 SEP 2020 11:00
Nasopharyngeal Swab 2	No		

US3462091

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

97.7 °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

08 SEP 2020 11:40

PC Open Date & Time

08 SEP 2020 11:25

PC Close Date & Time

08 SEP 2020 13:55

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °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	08 SEP 2020 18:42
PC Open Date & Time	08 SEP 2020 14:50
PC Close Date & Time	09 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

09 SEP 2020 17:57

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

97.6 °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

10 SEP 2020 17:33

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

11 SEP 2020 18:51

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 20:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

13 SEP 2020 19:45

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 17:48

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

08 SEP 2020 11:40

PC Open Date & Time

08 SEP 2020 11:25

PC Close Date & Time

08 SEP 2020 13:55

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

08 SEP 2020 18:43

PC Open Date & Time

08 SEP 2020 14:50

PC Close Date & Time

09 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

09 SEP 2020 17:57

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

10 SEP 2020 17:33

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

11 SEP 2020 18:51

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

12 SEP 2020 20:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

13 SEP 2020 19:45

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

14 SEP 2020 17:48

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 11:41
PC Open Date & Time	08 SEP 2020 11:25
PC Close Date & Time	08 SEP 2020 13:55

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 18:43
PC Open Date & Time	08 SEP 2020 14:50
PC Close Date & Time	09 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	09 SEP 2020 17:58
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	10 SEP 2020 17:34
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	11 SEP 2020 18:51
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	12 SEP 2020 20:36
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	13 SEP 2020 19:45
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

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 ☒

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

Yes ☐	
PC Time stamp	14 SEP 2020 17:49
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3462091

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462091

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

Was Contact Attempted?

Yes ☒

No ☐

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

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462091

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462091

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

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.

US3462091

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 OCT 2020

Collection time (00:00-23:59)

07:31 (24 HR)

Collection date and time (derived)

5 OCT 2020 07:31

US3462091

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	14 OCT 2020 19:41:59
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 19:03:38

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 16:44:16

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 22:23:18

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

16 NOV 2020 23:07:38

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

11 OCT 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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17 JAN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 166

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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24 JAN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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31 JAN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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03 FEB 2021 00:01

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07 FEB 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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10 FEB 2021 00:01

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14 FEB 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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21 FEB 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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28 FEB 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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21 MAR 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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24 MAR 2021 00:01

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28 MAR 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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04 APR 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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07 APR 2021 00:01

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11 APR 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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28 NOV 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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19 DEC 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

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26 DEC 2021 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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02 JAN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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16 JAN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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26 JAN 2022 00:01

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30 JAN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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06 FEB 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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27 FEB 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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10 APR 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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17 APR 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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24 APR 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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05 JUN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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12 JUN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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19 JUN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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22 JUN 2022 00:01

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26 JUN 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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10 JUL 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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17 JUL 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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20 JUL 2022 00:01

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24 JUL 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

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27 JUL 2022 00:01

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31 JUL 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3462091

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462091

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:29:21

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3462091

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:29:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3462091

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:29:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

AEID	USA-US093-2020-MRNA-1273-P30 1000007
Adverse event	NECK PAIN
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	09 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	14 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	14 OCT 2020
Admitted to ICU?	Yes ☐ No ☐ Unknown ☒
Number of Days in ICU	
v6.020 DTW (1102)	341 of 1974

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

PER PATIENT REPORT OVER
PHONE ON 19OCT20 AT 13:22,
ON 09OCT20 PATIENT HAD
SYMPTOMS OF SEVERE
NECK/BACK PAIN STARTING
WITH NO KNOWN
TRIGGER/INCIDENT. WIFE
DROVE PATIENT TO ER AND
PATIENT WAS HOSPITALIZED
FOR 5 NIGHTS. PER PATIENT, 3
SPINAL TAPS WERE DONE, AND
AN ECOLI AND COVID TEST
PERFORMED, AND ALL
FINDINGS WERE NEGATIVE.
PER PATIENT, OXYCODONE, AN
ANTIBIOTIC, A MUSCLE
RELAXANT AND TYLENOL
WERE PRESCRIBED, AND
MORPHINE GIVEN VIA IV
FLUIDS. PATIENT WAS ON IV
FLUIDS 10/9-10/14. PATIENT
DOES RECALL ALL
MEDICATION DETAILS.
PATIENT FEELS MUCH
IMPROVED AND LAST DOSE OF
ANTIBIOTICS AND PAIN
MEDICATION WAS 10/16/2020.
MEDICAL RECORDS WILL BE
REQUESTED FOR MORE
DETAILS.

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)	0

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT HAD AN SAE OF SEVER NECK PAIN WITH HOSPITALIZATION 10/9-10/14/20, BUT CONDITION GREATLY IMPROVED ON 10/14/20 AND PATIENT WAS RELEASED FROM HOSPITAL. NECK PAIN IS STILL ONGOING AND PATIENT STILL TAKING TYLENOL AND OXYCODONE AS NEEDED, BUT FULLY FUNCTIONAL.

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

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)	

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:29:21

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

Yes ☒

No ☐

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

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION
Dose per administration	60
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 ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		26 JUN 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMINARY DISEASE EXACERBATION
Dose per administration	20
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 ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		29 JUN 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ☒
Indication	TYPE II DIABETES
Dose per administration	2000
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	LOSARTAN
Prophylaxis	Yes ☐ No ☒
Indication	CONGESTIVE HEART FAILURE
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC HEART FAILURE
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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	TORSEMIDE
Prophylaxis	Yes ☐ No ☒
Indication	BILATERAL LEG EDEMA
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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	POTASSIUM
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	BROVANA
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMINARY DISEASE
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	NEBULIZER
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 ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	STIOLTO
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC OBSTRUCTIVE PULMINARY DISEASE
Dose per administration	1
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 ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	JARDIANCE
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC HEARY FAILURE
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	10 JUL 2020
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ☒
Indication	NECK PAIN
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	DOSE UNKNOWN
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	CONTINUOUS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		9 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	OXYCODONE
Prophylaxis	Yes ☐ No ☒
Indication	NECK PAIN
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		11 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	NECK PAIN
Dose per administration	650
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		9 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	MUSCLE RELAXANT
Prophylaxis	Yes ☐ No ☒
Indication	NECK PAIN
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		9 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

Name of Medication	ANTIBIOTIC
Prophylaxis	Yes ☐ No ☒
Indication	UNKNOWN
Dose per administration	UNKNOWN
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN. WAITING FOR MEDICAL RECORDS.
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 ☐

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:29:21

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:29:21

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 OCT 2020	SPINAL TAP	Adverse Event	
09 OCT 2020	SPINAL TAP	Adverse Event	
9 OCT 2020	SPINAL TAP	Adverse Event	
9 OCT 2020	NASAL SWAB	Adverse Event	
9 OCT 2020	ECOLI TEST	Adverse Event	
9 OCT 2020	ELECTROCARDIOGRAM	Adverse Event	
9 OCT 2020	IV FLUIDS	Adverse Event	

US3462091

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:29:21

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

US3462091

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:29:21

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 ☐

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

SAEID	USA-US093-2020-MRNA-1273-P301000007
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:29:21

SAEID	USA-US093-2020-MRNA-1273-P301000007
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	20/OCT/2020 16:47
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

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:29:21

SAEID	USA-US093-2020-MRNA-1273-P301000007
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/NOV/2020 06:05
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

US3462091 (Prod: Crisor, LLC)

US3462091

Form: Participant Creation

Generated On: 26 Nov 2020 09:29:21

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3462091'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 16:34:50

US3462091

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:08:28

US3462091

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 16:34:52

US3462091

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Aug 2020 18:08:28

US3462091

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	10 Aug 2020 18:08:28

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 16:34:53

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[Age](#)

Audit	User	Time (GMT)
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	19 Oct 2020 23:53:58
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED] [REDACTED]	19 Oct 2020 23:53:58
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	10 Aug 2020 18:09:04
User entered '67'	(b) (4), (b) (6) [REDACTED]	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '66'	System	10 Aug 2020 18:09:04

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:29:21

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:08:52

US3462091

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 18:09:04

US3462091

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	10 Aug 2020 18:09:04

US3462091

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Aug 2020 18:09:04

US3462091

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	10 Aug 2020 18:09:04

US3462091

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:09:04

US3462091

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:09:04

US3462091

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:09:04

US3462091

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 18:09:04

US3462091

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 16:34:52

US3462091

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:29:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 18:09:08

US3462091

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:09:08

US3462091

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:29:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:05

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 11:44:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 11:44:20
Data point term sent to Coder	System	12 Aug 2020 16:21:25
User entered 'RIGHT EYE CATARACT'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		19 Oct 2020 23:54:43
User entered 'UN (b) (6) 1953' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 23:54:43
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	12 Aug 2020 16:20:38
User entered 'UN UNK 1953'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered (b) (6) 1953'	System	19 Oct 2020 23:54:43
User entered 'Jan 1953'	System	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '1953'	System	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:20:38

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Left cataract - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 16:22:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	12 Aug 2020 16:22:08
Data point term sent to Coder	System	12 Aug 2020 16:21:26
User entered 'LEFT EYE CATARACT'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:20:57

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 13:59:00
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Conmed has been entered.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 19:09:41
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:06:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:17
Data point term sent to Coder	System	12 Aug 2020 16:24:29
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Daniel Hamlin (b) (4)	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Danuel Hamlin (b) (4)	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2015'	System	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:23:30

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:42:30
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 23:55:23
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:06:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease exacerbation - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 16:25:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 16:25:11
Data point term sent to Coder	System	12 Aug 2020 16:24:30
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '24 Jun 2020'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '29 Jun 2020'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Aug 2020 16:24:17

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 21:10:36
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 23:55:37
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:06:47
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:23
Data point term sent to Coder	System	12 Aug 2020 16:25:32
User entered 'TYPE 2 DIABETES'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:24:37

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Shoulder injury - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:24
Data point term sent to Coder	System	12 Aug 2020 16:25:31
User entered 'LEFT SHOULDER DAMAGE'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of LEFT SHOULDER DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 13:59:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:40:13
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of LEFT SHOULDER DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:39:59
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of LEFT SHOULDER DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:07:03
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2013' reason for change:	(b) (4), (b) (6)	07 Nov 2020 20:40:13
Data Entry Error		
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2013'	System	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	07 Nov 2020 20:40:13
User entered empty.	System	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2013'	System	07 Nov 2020 20:40:13
User entered empty.	System	12 Aug 2020 16:24:55

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Joint injury, LLT: Knee injury - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:26:24
Data point term sent to Coder	System	12 Aug 2020 16:25:32
User entered 'BILATERAL KNEE DAMAGE'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2007'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of BILATERAL KNEE DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 13:59:20
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of BILATERAL KNEE DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' answered with 'NOTED, HOWEVER, THE CONDITION KNEE DAMAGE IS NOT THE EVENT BUT THE CONDITON OF THIS PERSON'S KNEE. THE DAMAGE IS UNREPAIRED AND STILL THERE. PLEASE CONTINUE TO ADVISE IF AN END DATE IS STILL THOUGH NECESSARY.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:43:52
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. The effects of BILATERAL KNEE DAMAGE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:07:20
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2007'	System	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:25:08

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Ruptured intervertebral disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:24:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 13:24:20
Data point term sent to Coder	System	12 Aug 2020 16:25:32
User entered 'LOWER BACK RUPTURED DISCS'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2004'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2004'	System	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:25:25

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallbladder stones - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:27:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 16:27:14
Data point term sent to Coder	System	12 Aug 2020 16:26:33
User entered 'GALL BLADDER STONES'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2008'	System	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:25:42

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '09:46'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 09:46'	System	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '183' cm	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35
DataPoint set to visible.	System	10 Aug 2020 18:09:08

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '142.0' kg	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35
DataPoint set to visible.	System	10 Aug 2020 18:09:08

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '42.40198'	System	16 Sep 2020 23:50:00
User entered '42.4'	System	12 Aug 2020 16:26:35
DataPoint set to visible.	System	10 Aug 2020 18:09:08

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	12 Aug 2020 16:26:35
DataPoint set to visible.	System	10 Aug 2020 18:09:08

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered '97.9' F	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4) [REDACTED]	02 Oct 2020 21:29:44
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4) [REDACTED]	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered '71'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered '12'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered '123'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:44
User entered '74'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:26:35

US3462091

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:47

US3462091

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 12:23:20
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 18:23:08
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	12 Aug 2020 16:26:47

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:11:08
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

[Specify](#)

Audit	User	Time (GMT)
User entered 'patient works in a car shop with two co-workers, . Patient has 3-4 customers per week and works 5 days per week.'	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

[Other](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:29:21

[Specify](#)

Audit	User	Time (GMT)
User entered 'patient attend church twice weekly, with 100 or more other church members.'	(b) (4), (b) (6)	10 Aug 2020 18:11:08

US3462091

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 18:12:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 18:12:37
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 18:12:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:12:34

US3462091

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 18:12:34

US3462091

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Aug 2020 18:12:34

US3462091

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	10 Aug 2020 18:12:37
User entered empty.	System	10 Aug 2020 18:12:34

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 17:19:23

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:21

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:18:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:18:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 17:19:23
User entered '185134' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 17:19:23

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 17:19:23

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:13:05

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:13:05

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:13:05

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:21

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:13:05

US3462091

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:29:21

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 18:13:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:21

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:27:22
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:40:23
User entered '183' cm	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered '142.0' kg	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:21

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:27:22
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:40:23
User entered '183' cm	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered '142.0' kg	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '09:46'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 09:46'	System	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Pulse (xxx)

Audit	User	Time (GMT)
User entered '71'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '12'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:21

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:27:22
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:40:23
User entered '183' cm	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:29:21

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered '142.0' kg	Danuel Hamlin (b) (4)	12 Aug 2020 16:27:25

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '11:50'	Daniel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:50'	System	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 21:29:05
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '12'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '118'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 16:28:05

US3462091

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:19

US3462091

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:19

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10:43'	(b) (4), (b) (6)	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:43'	System	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 18:13:44

US3462091

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:45

US3462091

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:45

US3462091

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:31'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:45

US3462091

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:31'	System	12 Aug 2020 16:28:45

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:34'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:34'	System	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:28:56

US3462091

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	12 Aug 2020 16:29:01

US3462091

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:29:01

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:51:03', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '67abc14c-3ce0-41dc-b3cd-56da7614e125'	System	10 Aug 2020 18:51:29
User entered 'Yes (Y)'	System	10 Aug 2020 18:51:29

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:50:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '67abc14c-3ce0-41dc-b3cd-56da7614e125'	System	10 Aug 2020 18:51:29
User entered '98.4'	System	10 Aug 2020 18:51:29

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:50:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '67abc14c-3ce0-41dc-b3cd-56da7614e125'	System	10 Aug 2020 18:51:29
User entered 'No (N)'	System	10 Aug 2020 18:51:29

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:51:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '67abc14c-3ce0-41dc-b3cd-56da7614e125'	System	10 Aug 2020 18:51:29
User entered '10 Aug 2020 11:51'	System	10 Aug 2020 18:51:29

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:03'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 13:33'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:04:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4c1de05-d2b1-4b30-bc43-f579e7c2f528'	System	11 Aug 2020 00:04:57
User entered 'Yes (Y)'	System	11 Aug 2020 00:04:57

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:04:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4c1de05-d2b1-4b30-bc43-f579e7c2f528'	System	11 Aug 2020 00:04:57
User entered '98.7'	System	11 Aug 2020 00:04:57

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:04:46', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4c1de05-d2b1-4b30-bc43-f579e7c2f528'	System	11 Aug 2020 00:04:57
User entered 'No (N)'	System	11 Aug 2020 00:04:57

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:04:55', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f4c1de05-d2b1-4b30-bc43-f579e7c2f528'	System	11 Aug 2020 00:04:57
User entered '10 Aug 2020 17:04'	System	11 Aug 2020 00:04:57

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 14:28'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 2'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:08:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd95f7266-377a-4f25-a1f1-9d9b249f2516'	System	12 Aug 2020 01:08:59
User entered 'Yes (Y)'	System	12 Aug 2020 01:08:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:08:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd95f7266-377a-4f25-a1f1-9d9b249f2516'	System	12 Aug 2020 01:08:59
User entered '98.2'	System	12 Aug 2020 01:08:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:08:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd95f7266-377a-4f25-a1f1-9d9b249f2516'	System	12 Aug 2020 01:08:59
User entered 'No (N)'	System	12 Aug 2020 01:08:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:08:57', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd95f7266-377a-4f25-a1f1-9d9b249f2516'	System	12 Aug 2020 01:08:59
User entered '11 Aug 2020 18:08'	System	12 Aug 2020 01:08:59

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 3'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:02:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a805ba1f-238a-442e-9377-74deb60bd2fc'	System	13 Aug 2020 01:03:10
User entered 'Yes (Y)'	System	13 Aug 2020 01:03:10

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:02:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a805ba1f-238a-442e-9377-74deb60bd2fc'	System	13 Aug 2020 01:03:10
User entered '98.7'	System	13 Aug 2020 01:03:10

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a805ba1f-238a-442e-9377-74deb60bd2fc'	System	13 Aug 2020 01:03:10
User entered 'No (N)'	System	13 Aug 2020 01:03:10

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a805ba1f-238a-442e-9377-74deb60bd2fc'	System	13 Aug 2020 01:03:10
User entered '12 Aug 2020 18:03'	System	13 Aug 2020 01:03:10

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 4'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:02:33', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7607fda1-a1e2-4deb-bcbc-0ef1fef4281e'	System	14 Aug 2020 00:03:06
User entered 'Yes (Y)'	System	14 Aug 2020 00:03:06

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:02:53', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7607fda1-a1e2-4deb-bcbc-0ef1fef4281e'	System	14 Aug 2020 00:03:06
User entered '97.3'	System	14 Aug 2020 00:03:06

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:02:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7607fda1-a1e2-4deb-bcbc-0ef1fef4281e'	System	14 Aug 2020 00:03:06
User entered 'No (N)'	System	14 Aug 2020 00:03:06

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:05', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7607fda1-a1e2-4deb-bcbc-0ef1fef4281e'	System	14 Aug 2020 00:03:06
User entered '13 Aug 2020 17:03'	System	14 Aug 2020 00:03:06

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 5'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:14:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4096e8c3-483d-4c02-a37b-e5954373e108'	System	15 Aug 2020 03:15:14
User entered 'Yes (Y)'	System	15 Aug 2020 03:15:14

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4096e8c3-483d-4c02-a37b-e5954373e108'	System	15 Aug 2020 03:15:14
User entered '97.2'	System	15 Aug 2020 03:15:14

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4096e8c3-483d-4c02-a37b-e5954373e108'	System	15 Aug 2020 03:15:14
User entered 'No (N)'	System	15 Aug 2020 03:15:14

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4096e8c3-483d-4c02-a37b-e5954373e108'	System	15 Aug 2020 03:15:14
User entered '14 Aug 2020 20:15'	System	15 Aug 2020 03:15:14

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 6'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7e9d5bf1-13f3-44d6-8453-c7389684815f'	System	16 Aug 2020 01:31:54
User entered 'Yes (Y)'	System	16 Aug 2020 01:31:54

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7e9d5bf1-13f3-44d6-8453-c7389684815f'	System	16 Aug 2020 01:31:54
User entered '97.9'	System	16 Aug 2020 01:31:54

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:45', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7e9d5bf1-13f3-44d6-8453-c7389684815f'	System	16 Aug 2020 01:31:54
User entered 'No (N)'	System	16 Aug 2020 01:31:54

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7e9d5bf1-13f3-44d6-8453-c7389684815f'	System	16 Aug 2020 01:31:54
User entered '15 Aug 2020 18:31'	System	16 Aug 2020 01:31:54

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 7'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'fd2597aa-95bb-4b6c-a2fe-6f0fddb75aa9'	System	17 Aug 2020 00:01:30
User entered 'Yes (Y)'	System	17 Aug 2020 00:01:30

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'fd2597aa-95bb-4b6c-a2fe-6f0fddb75aa9'	System	17 Aug 2020 00:01:30
User entered '98.8'	System	17 Aug 2020 00:01:30

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'fd2597aa-95bb-4b6c-a2fe-6f0fddb75aa9'	System	17 Aug 2020 00:01:30
User entered 'No (N)'	System	17 Aug 2020 00:01:30

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:29', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'fd2597aa-95bb-4b6c-a2fe-6f0fddb75aa9'	System	17 Aug 2020 00:01:30
User entered '16 Aug 2020 17:01'	System	17 Aug 2020 00:01:30

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:04', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a68c6e0a-9920-4cf5-a34f-f90f016bf0e9'	System	10 Aug 2020 18:52:37
User entered 'None (1)'	System	10 Aug 2020 18:52:37

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a68c6e0a-9920-4cf5-a34f-f90f016bf0e9'	System	10 Aug 2020 18:52:37
User entered 'No (N)'	System	10 Aug 2020 18:52:37

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a68c6e0a-9920-4cf5-a34f-f90f016bf0e9'	System	10 Aug 2020 18:52:37
User entered 'No (N)'	System	10 Aug 2020 18:52:37

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a68c6e0a-9920-4cf5-a34f-f90f016bf0e9'	System	10 Aug 2020 18:52:37
User entered 'None (1)'	System	10 Aug 2020 18:52:37

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:35', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'a68c6e0a-9920-4cf5-a34f-f90f016bf0e9'	System	10 Aug 2020 18:52:37
User entered '10 Aug 2020 11:52'	System	10 Aug 2020 18:52:37

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:03'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 13:33'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7ee70210-fe09-42b3-b2e7-d8ffb8c1ea62'	System	11 Aug 2020 00:05:21
User entered 'None (1)'	System	11 Aug 2020 00:05:21

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7ee70210-fe09-42b3-b2e7-d8ffb8c1ea62'	System	11 Aug 2020 00:05:21
User entered 'No (N)'	System	11 Aug 2020 00:05:21

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:09', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7ee70210-fe09-42b3-b2e7-d8ffb8c1ea62'	System	11 Aug 2020 00:05:21
User entered 'No (N)'	System	11 Aug 2020 00:05:21

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7ee70210-fe09-42b3-b2e7-d8ffb8c1ea62'	System	11 Aug 2020 00:05:21
User entered 'None (1)'	System	11 Aug 2020 00:05:21

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7ee70210-fe09-42b3-b2e7-d8ffb8c1ea62'	System	11 Aug 2020 00:05:21
User entered '10 Aug 2020 17:05'	System	11 Aug 2020 00:05:21

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 14:28'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 2'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:04', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '620a520b-f1c5-4360-9f70-bed200f3165b'	System	12 Aug 2020 01:09:23
User entered 'None (1)'	System	12 Aug 2020 01:09:23

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '620a520b-f1c5-4360-9f70-bed200f3165b'	System	12 Aug 2020 01:09:23
User entered 'No (N)'	System	12 Aug 2020 01:09:23

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '620a520b-f1c5-4360-9f70-bed200f3165b'	System	12 Aug 2020 01:09:23
User entered 'No (N)'	System	12 Aug 2020 01:09:23

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:16', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '620a520b-f1c5-4360-9f70-bed200f3165b'	System	12 Aug 2020 01:09:23
User entered 'None (1)'	System	12 Aug 2020 01:09:23

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '620a520b-f1c5-4360-9f70-bed200f3165b'	System	12 Aug 2020 01:09:23
User entered '11 Aug 2020 18:09'	System	12 Aug 2020 01:09:23

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 3'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3b99df46-d4f5-4e1c-b1ba-3dc4fe3de0d7'	System	13 Aug 2020 01:03:32
User entered 'None (1)'	System	13 Aug 2020 01:03:32

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3b99df46-d4f5-4e1c-b1ba-3dc4fe3de0d7'	System	13 Aug 2020 01:03:32
User entered 'No (N)'	System	13 Aug 2020 01:03:32

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:17', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3b99df46-d4f5-4e1c-b1ba-3dc4fe3de0d7'	System	13 Aug 2020 01:03:32
User entered 'No (N)'	System	13 Aug 2020 01:03:32

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3b99df46-d4f5-4e1c-b1ba-3dc4fe3de0d7'	System	13 Aug 2020 01:03:32
User entered 'None (1)'	System	13 Aug 2020 01:03:32

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3b99df46-d4f5-4e1c-b1ba-3dc4fe3de0d7'	System	13 Aug 2020 01:03:32
User entered '12 Aug 2020 18:03'	System	13 Aug 2020 01:03:32

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 4'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:10', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '99156e43-d32e-4793-9d55-c4ffe06c2dee'	System	14 Aug 2020 00:03:31
User entered 'None (1)'	System	14 Aug 2020 00:03:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:17', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '99156e43-d32e-4793-9d55-c4ffe06c2dee'	System	14 Aug 2020 00:03:31
User entered 'No (N)'	System	14 Aug 2020 00:03:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '99156e43-d32e-4793-9d55-c4ffe06c2dee'	System	14 Aug 2020 00:03:31
User entered 'No (N)'	System	14 Aug 2020 00:03:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:24', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '99156e43-d32e-4793-9d55-c4ffe06c2dee'	System	14 Aug 2020 00:03:31
User entered 'None (1)'	System	14 Aug 2020 00:03:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '99156e43-d32e-4793-9d55-c4ffe06c2dee'	System	14 Aug 2020 00:03:31
User entered '13 Aug 2020 17:03'	System	14 Aug 2020 00:03:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 5'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:16', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4af7ee29-e3f5-4ae3-a47c-4db48cbc2fa0'	System	15 Aug 2020 03:15:31
User entered 'None (1)'	System	15 Aug 2020 03:15:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4af7ee29-e3f5-4ae3-a47c-4db48cbc2fa0'	System	15 Aug 2020 03:15:31
User entered 'No (N)'	System	15 Aug 2020 03:15:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4af7ee29-e3f5-4ae3-a47c-4db48cbc2fa0'	System	15 Aug 2020 03:15:31
User entered 'No (N)'	System	15 Aug 2020 03:15:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4af7ee29-e3f5-4ae3-a47c-4db48cbc2fa0'	System	15 Aug 2020 03:15:31
User entered 'None (1)'	System	15 Aug 2020 03:15:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '4af7ee29-e3f5-4ae3-a47c-4db48cbc2fa0'	System	15 Aug 2020 03:15:31
User entered '14 Aug 2020 20:15'	System	15 Aug 2020 03:15:31

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 6'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9f8dfd2c-e391-49cb-a633-d8f0983fbb0d'	System	16 Aug 2020 01:32:15
User entered 'None (1)'	System	16 Aug 2020 01:32:15

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:31:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9f8dfd2c-e391-49cb-a633-d8f0983fbb0d'	System	16 Aug 2020 01:32:15
User entered 'No (N)'	System	16 Aug 2020 01:32:15

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:03', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9f8dfd2c-e391-49cb-a633-d8f0983fbb0d'	System	16 Aug 2020 01:32:15
User entered 'No (N)'	System	16 Aug 2020 01:32:15

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9f8dfd2c-e391-49cb-a633-d8f0983fbb0d'	System	16 Aug 2020 01:32:15
User entered 'None (1)'	System	16 Aug 2020 01:32:15

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '9f8dfd2c-e391-49cb-a633-d8f0983fbb0d'	System	16 Aug 2020 01:32:15
User entered '15 Aug 2020 18:32'	System	16 Aug 2020 01:32:15

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 7'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:33', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c60caaa4-063e-4924-ae02-6717b1d65f8b'	System	17 Aug 2020 00:01:53
User entered 'None (1)'	System	17 Aug 2020 00:01:53

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c60caaa4-063e-4924-ae02-6717b1d65f8b'	System	17 Aug 2020 00:01:53
User entered 'No (N)'	System	17 Aug 2020 00:01:53

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:42', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c60caaa4-063e-4924-ae02-6717b1d65f8b'	System	17 Aug 2020 00:01:53
User entered 'No (N)'	System	17 Aug 2020 00:01:53

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c60caaa4-063e-4924-ae02-6717b1d65f8b'	System	17 Aug 2020 00:01:53
User entered 'None (1)'	System	17 Aug 2020 00:01:53

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c60caaa4-063e-4924-ae02-6717b1d65f8b'	System	17 Aug 2020 00:01:53
User entered '16 Aug 2020 17:01'	System	17 Aug 2020 00:01:53

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:48', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'None (0)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:52:58', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'None (0)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:01', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'None (0)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:04', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde'	System	10 Aug 2020 18:53:21
User entered 'None (0)'	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde'	System	10 Aug 2020 18:53:21
User entered 'None (0)'	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:10', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered 'None (0)'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde'	System	10 Aug 2020 18:53:21
User entered 'No (N)'	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T11:53:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e70a63ec-0c09-4bd0-a97b-740e93735bde' User entered '10 Aug 2020 11:53'	System	10 Aug 2020 18:53:21
	System	10 Aug 2020 18:53:21

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:03'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 13:33'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:23', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:29', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:32', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'None (0)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:46', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered 'No (N)'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-10T17:05:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'b7fb5498-c992-47c1-8034-716a4090af7c'	System	11 Aug 2020 00:05:53
User entered '10 Aug 2020 17:05'	System	11 Aug 2020 00:05:53

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 14:28'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 2'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'None (0)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:48', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered 'No (N)'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-11T18:09:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2b803181-83da-4479-a502-9962a331e45b'	System	12 Aug 2020 01:09:55
User entered '11 Aug 2020 18:09'	System	12 Aug 2020 01:09:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 3'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:32', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:35', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:42', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:45', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'None (0)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:48', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered 'No (N)'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-12T18:03:52', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '1558eac2-18f3-4f38-a166-86df0801b679'	System	13 Aug 2020 01:03:55
User entered '12 Aug 2020 18:03'	System	13 Aug 2020 01:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 4'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:35', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:40', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:45', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:47', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'None (0)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:50', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered 'No (N)'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-13T17:03:52', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '7bfadf65-fd8f-4d2b-a5f8-2b45a44d722c'	System	14 Aug 2020 00:03:55
User entered '13 Aug 2020 17:03'	System	14 Aug 2020 00:03:55

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 5'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'None (0)'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:36', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'None (0)'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'None (0)'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:40', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'None (0)'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:42', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'None (0)'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:45', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec' User entered 'None (0)'	System	15 Aug 2020 03:15:52
	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:48', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered 'No (N)'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-14T20:15:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8adba634-4865-468d-a5e4-19c31a69b4ec'	System	15 Aug 2020 03:15:52
User entered '14 Aug 2020 20:15'	System	15 Aug 2020 03:15:52

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 6'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:46', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:53', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'None (0)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered 'No (N)'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-15T18:32:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'e613dd57-0081-4ddb-8dd8-4b5e229dff87'	System	16 Aug 2020 01:33:04
User entered '15 Aug 2020 18:32'	System	16 Aug 2020 01:33:04

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 7'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:54', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:57', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:01:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:02:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:02:05', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:02:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'None (0)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:02:10', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered 'No (N)'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-08-16T17:02:13', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '441e3efb-bb7d-49cd-89d9-cf255b91d050'	System	17 Aug 2020 00:02:14
User entered '16 Aug 2020 17:02'	System	17 Aug 2020 00:02:14

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:13:44

US3462091

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:21:42

US3462091

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 18:21:42

US3462091

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 18:21:42

US3462091

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:21:42

US3462091

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:21:46

US3462091

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:21:46

US3462091

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:22:06

US3462091

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 18:22:06

US3462091

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 18:22:06

US3462091

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:22:06

US3462091

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:22:10

US3462091

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:22:10

US3462091

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:22:21

US3462091

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:22:21

US3462091

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 18:22:21

US3462091

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:22:21

US3462091

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:22:50

US3462091

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:22:50

US3462091

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:23:08

US3462091

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:23:08

US3462091

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 18:23:08

US3462091

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	08 Sep 2020 18:23:08

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10:23'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 10:23'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '16'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:29:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '11:42'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:42'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '12'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '117'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '75'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:29:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 18:57:25

US3462091

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:31

US3462091

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:31

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '11:05'	(b) (4), (b) (6)	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 11:05'	System	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:23:29

US3462091

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:59

US3462091

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:59

US3462091

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:58'	Danuel Hamlin (b) (4)	21 Sep 2020 18:57:59

US3462091

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 10:58'	System	21 Sep 2020 18:57:59

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:29:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Sep 2020 18:55:52
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		21 Sep 2020 18:55:52
User entered '08 Sep 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4) [REDACTED]	21 Sep 2020 18:55:52
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Sep 2020 18:55:27
User entered '11 Sep 2020'	Danuel Hamlin (b) (4) [REDACTED]	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:00'	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:00'	System	21 Sep 2020 18:55:52
User entered '11 Sep 2020 11:00'	System	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:21

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:02:48
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:02:48
User entered '11:00'	Danuel Hamlin (b) (4)	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:02:48
User entered '08 Sep 2020 11:00'	System	21 Sep 2020 18:55:52
User entered '11 Sep 2020 11:00'	System	21 Sep 2020 18:55:27

US3462091

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	21 Sep 2020 18:58:13

US3462091

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:58:13

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:39:55', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '97df93c2-e4ce-4585-8977-7eb592dff423'	System	08 Sep 2020 18:40:25
User entered 'Yes (Y)'	System	08 Sep 2020 18:40:25

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '97df93c2-e4ce-4585-8977-7eb592dff423'	System	08 Sep 2020 18:40:25
User entered '97.7'	System	08 Sep 2020 18:40:25

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '97df93c2-e4ce-4585-8977-7eb592dff423'	System	08 Sep 2020 18:40:25
User entered 'No (N)'	System	08 Sep 2020 18:40:25

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:23', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '97df93c2-e4ce-4585-8977-7eb592dff423'	System	08 Sep 2020 18:40:25
User entered '08 Sep 2020 11:40'	System	08 Sep 2020 18:40:25

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:25'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 13:55'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2f57a612-f76a-4318-ba2b-3227dd196567'	System	09 Sep 2020 01:42:40
User entered 'Yes (Y)'	System	09 Sep 2020 01:42:40

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2f57a612-f76a-4318-ba2b-3227dd196567'	System	09 Sep 2020 01:42:40
User entered '98.0'	System	09 Sep 2020 01:42:40

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2f57a612-f76a-4318-ba2b-3227dd196567'	System	09 Sep 2020 01:42:40
User entered 'No (N)'	System	09 Sep 2020 01:42:40

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:37', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2f57a612-f76a-4318-ba2b-3227dd196567'	System	09 Sep 2020 01:42:40
User entered '08 Sep 2020 18:42'	System	09 Sep 2020 01:42:40

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 14:50'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 2'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:56:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '352ef134-8095-43a8-ab9e-15743b6ab9b6'	System	10 Sep 2020 00:57:15
User entered 'Yes (Y)'	System	10 Sep 2020 00:57:15

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:56:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '352ef134-8095-43a8-ab9e-15743b6ab9b6'	System	10 Sep 2020 00:57:15
User entered '98.7'	System	10 Sep 2020 00:57:15

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '352ef134-8095-43a8-ab9e-15743b6ab9b6'	System	10 Sep 2020 00:57:15
User entered 'No (N)'	System	10 Sep 2020 00:57:15

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '352ef134-8095-43a8-ab9e-15743b6ab9b6'	System	10 Sep 2020 00:57:15
User entered '09 Sep 2020 17:57'	System	10 Sep 2020 00:57:15

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 3'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6076c857-ae96-4509-b006-be88f3528466'	System	11 Sep 2020 00:33:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:33:23

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6076c857-ae96-4509-b006-be88f3528466'	System	11 Sep 2020 00:33:23
User entered '97.6'	System	11 Sep 2020 00:33:23

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:17', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6076c857-ae96-4509-b006-be88f3528466'	System	11 Sep 2020 00:33:23
User entered 'No (N)'	System	11 Sep 2020 00:33:23

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6076c857-ae96-4509-b006-be88f3528466'	System	11 Sep 2020 00:33:23
User entered '10 Sep 2020 17:33'	System	11 Sep 2020 00:33:23

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 4'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:50:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '87668b55-6ea2-4ddd-b490-d30d0b949d29'	System	12 Sep 2020 01:51:07
User entered 'Yes (Y)'	System	12 Sep 2020 01:51:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:50:54', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '87668b55-6ea2-4ddd-b490-d30d0b949d29'	System	12 Sep 2020 01:51:07
User entered '98.2'	System	12 Sep 2020 01:51:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:00', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '87668b55-6ea2-4ddd-b490-d30d0b949d29'	System	12 Sep 2020 01:51:07
User entered 'No (N)'	System	12 Sep 2020 01:51:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:03', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '87668b55-6ea2-4ddd-b490-d30d0b949d29'	System	12 Sep 2020 01:51:07
User entered '11 Sep 2020 18:51'	System	12 Sep 2020 01:51:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 5'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '530f8505-96dd-4bc3-b5c9-321b14d80f2c'	System	13 Sep 2020 03:35:36
User entered 'Yes (Y)'	System	13 Sep 2020 03:35:36

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:25', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '530f8505-96dd-4bc3-b5c9-321b14d80f2c' User entered '97.0'	System	13 Sep 2020 03:35:36
	System	13 Sep 2020 03:35:36

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:30', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '530f8505-96dd-4bc3-b5c9-321b14d80f2c'	System	13 Sep 2020 03:35:36
User entered 'No (N)'	System	13 Sep 2020 03:35:36

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '530f8505-96dd-4bc3-b5c9-321b14d80f2c'	System	13 Sep 2020 03:35:36
User entered '12 Sep 2020 20:35'	System	13 Sep 2020 03:35:36

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 6'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:44:48', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '573c6e9d-ac7d-4e7f-8f67-99181e39cac9'	System	14 Sep 2020 02:45:07
User entered 'Yes (Y)'	System	14 Sep 2020 02:45:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:44:55', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '573c6e9d-ac7d-4e7f-8f67-99181e39cac9' User entered '97.5'	System	14 Sep 2020 02:45:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:00', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '573c6e9d-ac7d-4e7f-8f67-99181e39cac9'	System	14 Sep 2020 02:45:07
User entered 'No (N)'	System	14 Sep 2020 02:45:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:04', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '573c6e9d-ac7d-4e7f-8f67-99181e39cac9' User entered '13 Sep 2020 19:45'	System	14 Sep 2020 02:45:07

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 7'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:47:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '71e9f416-ad43-4da0-a3d5-3db2aec34fbe'	System	15 Sep 2020 00:48:27
User entered 'Yes (Y)'	System	15 Sep 2020 00:48:27

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '71e9f416-ad43-4da0-a3d5-3db2aec34fbe' User entered '97.0'	System	15 Sep 2020 00:48:27
	System	15 Sep 2020 00:48:27

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '71e9f416-ad43-4da0-a3d5-3db2aec34fbe'	System	15 Sep 2020 00:48:27
User entered 'No (N)'	System	15 Sep 2020 00:48:27

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:25', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '71e9f416-ad43-4da0-a3d5-3db2aec34fbe'	System	15 Sep 2020 00:48:27
User entered '14 Sep 2020 17:48'	System	15 Sep 2020 00:48:27

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:29', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '54daf342-a3f5-4f0e-b1df-0144e3ae1c43'	System	08 Sep 2020 18:40:57
User entered 'None (1)'	System	08 Sep 2020 18:40:57

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '54daf342-a3f5-4f0e-b1df-0144e3ae1c43'	System	08 Sep 2020 18:40:57
User entered 'No (N)'	System	08 Sep 2020 18:40:57

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:46', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '54daf342-a3f5-4f0e-b1df-0144e3ae1c43'	System	08 Sep 2020 18:40:57
User entered 'No (N)'	System	08 Sep 2020 18:40:57

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:50', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '54daf342-a3f5-4f0e-b1df-0144e3ae1c43'	System	08 Sep 2020 18:40:57
User entered 'None (1)'	System	08 Sep 2020 18:40:57

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:54', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '54daf342-a3f5-4f0e-b1df-0144e3ae1c43'	System	08 Sep 2020 18:40:57
User entered '08 Sep 2020 11:40'	System	08 Sep 2020 18:40:57

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:25'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 13:55'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd8f7e0f0-7769-434d-93a6-942c18c7081b'	System	09 Sep 2020 01:43:09
User entered 'None (1)'	System	09 Sep 2020 01:43:09

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd8f7e0f0-7769-434d-93a6-942c18c7081b'	System	09 Sep 2020 01:43:09
User entered 'No (N)'	System	09 Sep 2020 01:43:09

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:42:55', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd8f7e0f0-7769-434d-93a6-942c18c7081b'	System	09 Sep 2020 01:43:09
User entered 'No (N)'	System	09 Sep 2020 01:43:09

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:01', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd8f7e0f0-7769-434d-93a6-942c18c7081b'	System	09 Sep 2020 01:43:09
User entered 'None (1)'	System	09 Sep 2020 01:43:09

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'd8f7e0f0-7769-434d-93a6-942c18c7081b'	System	09 Sep 2020 01:43:09
User entered '08 Sep 2020 18:43'	System	09 Sep 2020 01:43:09

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 14:50'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 2'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6939b52b-194e-42e4-b96a-d98c6c083999'	System	10 Sep 2020 00:57:48
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 00:57:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:25', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6939b52b-194e-42e4-b96a-d98c6c083999'	System	10 Sep 2020 00:57:48
User entered 'No (N)'	System	10 Sep 2020 00:57:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:35', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6939b52b-194e-42e4-b96a-d98c6c083999'	System	10 Sep 2020 00:57:48
User entered 'No (N)'	System	10 Sep 2020 00:57:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6939b52b-194e-42e4-b96a-d98c6c083999'	System	10 Sep 2020 00:57:48
User entered 'None (1)'	System	10 Sep 2020 00:57:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:57:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '6939b52b-194e-42e4-b96a-d98c6c083999'	System	10 Sep 2020 00:57:48
User entered '09 Sep 2020 17:57'	System	10 Sep 2020 00:57:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 3'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:27', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '280d2bba-80e8-4724-8e8e-4fd34a3ff434'	System	11 Sep 2020 00:33:48
User entered 'None (1)'	System	11 Sep 2020 00:33:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '280d2bba-80e8-4724-8e8e-4fd34a3ff434'	System	11 Sep 2020 00:33:48
User entered 'No (N)'	System	11 Sep 2020 00:33:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '280d2bba-80e8-4724-8e8e-4fd34a3ff434'	System	11 Sep 2020 00:33:48
User entered 'No (N)'	System	11 Sep 2020 00:33:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '280d2bba-80e8-4724-8e8e-4fd34a3ff434'	System	11 Sep 2020 00:33:48
User entered 'None (1)'	System	11 Sep 2020 00:33:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '280d2bba-80e8-4724-8e8e-4fd34a3ff434'	System	11 Sep 2020 00:33:48
User entered '10 Sep 2020 17:33'	System	11 Sep 2020 00:33:48

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 4'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '09be0be8-500e-4acc-b958-a7ede2fb25ba'	System	12 Sep 2020 01:51:25
User entered 'None (1)'	System	12 Sep 2020 01:51:25

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '09be0be8-500e-4acc-b958-a7ede2fb25ba'	System	12 Sep 2020 01:51:25
User entered 'No (N)'	System	12 Sep 2020 01:51:25

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '09be0be8-500e-4acc-b958-a7ede2fb25ba' User entered 'No (N)'	System	12 Sep 2020 01:51:25

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '09be0be8-500e-4acc-b958-a7ede2fb25ba'	System	12 Sep 2020 01:51:25
User entered 'None (1)'	System	12 Sep 2020 01:51:25

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '09be0be8-500e-4acc-b958-a7ede2fb25ba'	System	12 Sep 2020 01:51:25
User entered '11 Sep 2020 18:51'	System	12 Sep 2020 01:51:25

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 5'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:40', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c78076d8-9295-4948-b726-3be388253857'	System	13 Sep 2020 03:35:58
User entered 'None (1)'	System	13 Sep 2020 03:35:58

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c78076d8-9295-4948-b726-3be388253857'	System	13 Sep 2020 03:35:58
User entered 'No (N)'	System	13 Sep 2020 03:35:58

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:47', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c78076d8-9295-4948-b726-3be388253857'	System	13 Sep 2020 03:35:58
User entered 'No (N)'	System	13 Sep 2020 03:35:58

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c78076d8-9295-4948-b726-3be388253857'	System	13 Sep 2020 03:35:58
User entered 'None (1)'	System	13 Sep 2020 03:35:58

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:54', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'c78076d8-9295-4948-b726-3be388253857'	System	13 Sep 2020 03:35:58
User entered '12 Sep 2020 20:35'	System	13 Sep 2020 03:35:58

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 6'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:09', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05e88540-a773-4205-b934-636c4f9a8909'	System	14 Sep 2020 02:45:28
User entered 'None (1)'	System	14 Sep 2020 02:45:28

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05e88540-a773-4205-b934-636c4f9a8909'	System	14 Sep 2020 02:45:28
User entered 'No (N)'	System	14 Sep 2020 02:45:28

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05e88540-a773-4205-b934-636c4f9a8909'	System	14 Sep 2020 02:45:28
User entered 'No (N)'	System	14 Sep 2020 02:45:28

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05e88540-a773-4205-b934-636c4f9a8909'	System	14 Sep 2020 02:45:28
User entered 'None (1)'	System	14 Sep 2020 02:45:28

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '05e88540-a773-4205-b934-636c4f9a8909'	System	14 Sep 2020 02:45:28
User entered '13 Sep 2020 19:45'	System	14 Sep 2020 02:45:28

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 7'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:29', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'adf7bbd2-69f2-4a4e-b51a-af938c3fb225'	System	15 Sep 2020 00:48:45
User entered 'None (1)'	System	15 Sep 2020 00:48:45

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'adf7bbd2-69f2-4a4e-b51a-af938c3fb225'	System	15 Sep 2020 00:48:45
User entered 'No (N)'	System	15 Sep 2020 00:48:45

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:36', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'adf7bbd2-69f2-4a4e-b51a-af938c3fb225'	System	15 Sep 2020 00:48:45
User entered 'No (N)'	System	15 Sep 2020 00:48:45

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'adf7bbd2-69f2-4a4e-b51a-af938c3fb225'	System	15 Sep 2020 00:48:45
User entered 'None (1)'	System	15 Sep 2020 00:48:45

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'adf7bbd2-69f2-4a4e-b51a-af938c3fb225'	System	15 Sep 2020 00:48:45
User entered '14 Sep 2020 17:48'	System	15 Sep 2020 00:48:45

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:40:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'None (0)'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'None (0)'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'None (0)'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:09', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'None (0)'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'None (0)'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'None (0)'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered 'No (N)'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T11:41:24', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '517ac53f-0bcd-48e6-9667-8fba71f76ba5'	System	08 Sep 2020 18:41:29
User entered '08 Sep 2020 11:41'	System	08 Sep 2020 18:41:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:25'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 13:55'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:20', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:25', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd'	System	09 Sep 2020 01:43:45
User entered 'None (0)'	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:32', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'None (0)'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:39', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered 'No (N)'	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-08T18:43:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '3c5a9071-68b0-42aa-b8dd-fd43d0d162dd' User entered '08 Sep 2020 18:43'	System	09 Sep 2020 01:43:45
	System	09 Sep 2020 01:43:45

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 14:50'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 2'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:12', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:19', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:21', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'None (0)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered 'No (N)'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-09T17:58:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '08c9cc99-6b00-413e-8e5e-4832a2c3f7e7'	System	10 Sep 2020 00:58:34
User entered '09 Sep 2020 17:58'	System	10 Sep 2020 00:58:34

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 3'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:51', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:53', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:56', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:33:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:34:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'None (0)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:34:07', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered 'No (N)'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-10T17:34:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2dfe906a-b947-4f42-91f3-3b83c4ec1893'	System	11 Sep 2020 00:34:13
User entered '10 Sep 2020 17:34'	System	11 Sep 2020 00:34:13

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 4'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'None (0)'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:29', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'None (0)'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'None (0)'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:33', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'None (0)'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:36', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'None (0)'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'None (0)'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered 'No (N)'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-11T18:51:45', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '0777e531-096d-4a31-a74e-d1c227d8e7cc'	System	12 Sep 2020 01:51:48
User entered '11 Sep 2020 18:51'	System	12 Sep 2020 01:51:48

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 5'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:35:58', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a'	System	13 Sep 2020 03:36:21
User entered 'None (0)'	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:01', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a'	System	13 Sep 2020 03:36:21
User entered 'None (0)'	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:03', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a'	System	13 Sep 2020 03:36:21
User entered 'None (0)'	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:06', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a' User entered 'None (0)'	System	13 Sep 2020 03:36:21
	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a'	System	13 Sep 2020 03:36:21
User entered 'None (0)'	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a'	System	13 Sep 2020 03:36:21
User entered 'None (0)'	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a'	System	13 Sep 2020 03:36:21
User entered 'No (N)'	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-12T20:36:16', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '2362bce7-32f1-4825-aa17-ed8ad7629d6a'	System	13 Sep 2020 03:36:21
User entered '12 Sep 2020 20:36'	System	13 Sep 2020 03:36:21

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 6'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:31', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:33', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:36', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:41', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e' User entered 'None (0)'	System	14 Sep 2020 02:45:53
	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:43', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e'	System	14 Sep 2020 02:45:53
User entered 'None (0)'	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:46', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e'	System	14 Sep 2020 02:45:53
User entered 'No (N)'	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-13T19:45:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'f599e003-9173-4594-bf09-01db62e1ed1e'	System	14 Sep 2020 02:45:53
User entered '13 Sep 2020 19:45'	System	14 Sep 2020 02:45:53

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:23:29
User entered 'Day 7'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:49', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf'	System	15 Sep 2020 00:49:19
User entered 'None (0)'	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:48:57', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf'	System	15 Sep 2020 00:49:19
User entered 'None (0)'	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:00', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf'	System	15 Sep 2020 00:49:19
User entered 'None (0)'	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:02', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf'	System	15 Sep 2020 00:49:19
User entered 'None (0)'	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:05', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf'	System	15 Sep 2020 00:49:19
User entered 'None (0)'	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf'	System	15 Sep 2020 00:49:19
User entered 'None (0)'	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:13', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf'	System	15 Sep 2020 00:49:19
User entered 'No (N)'	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-09-14T17:49:15', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'febc9fef-6328-4c3e-822f-53c68b3617cf'	System	15 Sep 2020 00:49:19
User entered '14 Sep 2020 17:49'	System	15 Sep 2020 00:49:19

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:23:29

US3462091

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:29:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:23:29

US3462091

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:47:05

US3462091

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 22:47:05

US3462091

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 22:47:05

US3462091

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:47:05

US3462091

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:47:09

US3462091

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 22:47:09

US3462091

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:47:21

US3462091

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 22:47:21

US3462091

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 22:47:21

US3462091

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:47:21

US3462091

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:47:24

US3462091

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 22:47:24

US3462091

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:47:38

US3462091

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 22:47:38

US3462091

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 22:47:38

US3462091

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:29:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:47:38

US3462091

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:47:41

US3462091

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 22:47:41

US3462091

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:47:52

US3462091

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '5 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 22:47:52

US3462091

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Oct 2020 22:47:52

US3462091

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:29:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	08 Oct 2020 22:47:52

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:29:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 23:05:08

US3462091

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 23:05:14

US3462091

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:29:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 23:05:14

US3462091

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 23:05:45

US3462091

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 23:05:45

US3462091

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '07:31'	(b) (4), (b) (6)	08 Oct 2020 23:05:45

US3462091

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '5 Oct 2020 07:31'	System	08 Oct 2020 23:05:45

US3462091

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 23:05:20

US3462091

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:29:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 23:05:20

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 64'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:39:26', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8'	System	15 Oct 2020 02:42:10
User entered 'Yes (Y)'	System	15 Oct 2020 02:42:10

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:39:36', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8'	System	15 Oct 2020 02:42:10
User entered 'No (N)'	System	15 Oct 2020 02:42:10

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:39:50', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8'	System	15 Oct 2020 02:42:10
User entered 'No (N)'	System	15 Oct 2020 02:42:10

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:41:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8'	System	15 Oct 2020 02:42:10
User entered 'Yes (Y)'	System	15 Oct 2020 02:42:10

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Please 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:41:44', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8'	System	15 Oct 2020 02:42:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Oct 2020 02:42:10

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-14T19:41:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '46b6cf4c-cbbf-417e-aebb-49381e9c2ba8' User entered '14 Oct 2020 19:41:59'	System	15 Oct 2020 02:42:10
	System	15 Oct 2020 02:42:10

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 71'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-19T19:03:22', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '5331bc50-d278-44a3-9abb-c72a7d635008'	System	20 Oct 2020 02:03:40
User entered 'No (N)'	System	20 Oct 2020 02:03:40

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-19T19:03:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '5331bc50-d278-44a3-9abb-c72a7d635008'	System	20 Oct 2020 02:03:40
User entered 'No (N)'	System	20 Oct 2020 02:03:40

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-19T19:03:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '5331bc50-d278-44a3-9abb-c72a7d635008'	System	20 Oct 2020 02:03:40
User entered '19 Oct 2020 19:03:38'	System	20 Oct 2020 02:03:40

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 78'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-26T16:43:59', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'acf8cc52-cfa1-4470-862d-adc64ab82977'	System	26 Oct 2020 23:44:21
User entered 'No (N)'	System	26 Oct 2020 23:44:21

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-26T16:44:11', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'acf8cc52-cfa1-4470-862d-adc64ab82977'	System	26 Oct 2020 23:44:21
User entered 'No (N)'	System	26 Oct 2020 23:44:21

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-10-26T16:44:16', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: 'acf8cc52-cfa1-4470-862d-adc64ab82977'	System	26 Oct 2020 23:44:21
User entered '26 Oct 2020 16:44:16'	System	26 Oct 2020 23:44:21

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 92'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-09T22:23:08', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8828587c-9fa3-46eb-b6c5-60bf55bd7f51'	System	10 Nov 2020 06:23:21
User entered 'No (N)'	System	10 Nov 2020 06:23:21

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-09T22:23:14', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8828587c-9fa3-46eb-b6c5-60bf55bd7f51'	System	10 Nov 2020 06:23:21
User entered 'No (N)'	System	10 Nov 2020 06:23:21

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-09T22:23:18', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '8828587c-9fa3-46eb-b6c5-60bf55bd7f51'	System	10 Nov 2020 06:23:21
User entered '09 Nov 2020 22:23:18'	System	10 Nov 2020 06:23:21

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered 'Day 99'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-16T23:07:28', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '594a50d3-ad92-475c-bddf-7c80da097e45'	System	17 Nov 2020 07:07:40
User entered 'No (N)'	System	17 Nov 2020 07:07:40

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

Have you been exposed to someone with 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 (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-16T23:07:34', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '594a50d3-ad92-475c-bddf-7c80da097e45'	System	17 Nov 2020 07:07:40
User entered 'No (N)'	System	17 Nov 2020 07:07:40

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AF8D3A4-11D6-4068-8EFE-9AB67C52AE7B)', Time: '2020-11-16T23:07:38', User OID: 'PatientReportedOutcome (US3462091)', ODM File OID: '594a50d3-ad92-475c-bddf-7c80da097e45' User entered '16 Nov 2020 23:07:38'	System	17 Nov 2020 07:07:40
	System	17 Nov 2020 07:07:40

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 18:13:44

US3462091

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 18:13:44
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 18:13:44

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Oct 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 Oct 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Oct 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Oct 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Oct 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Oct 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 17:13:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 17:13:55

US3462091

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:29:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:13:55
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 17:13:55

US3462091

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:29:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 21:50:25

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:46:44
User entered 'USA-US093-2020-mRNA-1273-P301000007'	System	20 Oct 2020 16:46:40
User entered 'New'	(b) (4), (b) (6)	20 Oct 2020 16:46:40

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. If etiology was not determined, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:04:21
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. If etiology was not determined, please state so.' answered with 'PATIENT REPORTS NO KNOWN CAUSE AND IS UNCLEAR ON DETAILS. WAITING FOPR MEDICAL RECORDS.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 20:01:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. If etiology was not determined, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 00:20:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:01:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:01:22
Data point term sent to Coder	System	19 Oct 2020 22:00:19
User entered 'neck pain'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '09 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:58:40
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 20:00:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:00:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:58:41
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).	(b) (4), (b) (6)	09 Nov 2020 11:04:25
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 'ADDED' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 20:01:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 20:00:37
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:00:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
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)	30 Oct 2020 00:16:23
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '09 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '14 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Oct 2020 21:59:37
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:47:26
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'ADDED' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 00:03:39
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:47:55
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'ADDED' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:03:31
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 00:03:48
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:04:32
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 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 20:03:43
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 20:00:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:00:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
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)	30 Oct 2020 00:16:50
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 21:59:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The subject was treated with antibiotics. Please provide the indication. ' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:51:16
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)	17 Nov 2020 21:51:02
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. If etiology was not determined, please state so. ' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:50:44
User opened query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:50:20
User opened query 'PV Query: Please provide results of spinal tap. ' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:50:03
User opened query 'PV Query: Please provide diagnostic test results (i.e, spinal CT/MRI, etc) performed in evaluation of the event. ' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:49:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:59:03
User closed query 'Per DM CLR: SAE narrative indicates OXYCODONE, AN ANTIBIOTIC, A MUSCLE RELAXANT AND TYLENOL WERE PRESCRIBED, AND MORPHONE GIVEN VIA IV FLUIDS were given. However, there are no corresponding ConMed record to match these information. Please update to record these medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:48:06
User closed query 'Per DM CLR: SAE Narrative indicates that the subject underwent 3 Spinal taps and an E. Coli test. However, there are no corresponding Concomitant Procedure record that match this information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:48:01
User closed query 'PV Query: The subject was treated with antibiotics. Please provide the indication.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:04:57

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide results of spinal tap.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:04:55
User closed query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:04:52
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)	09 Nov 2020 11:04:49
User closed query 'PV Query: Please provide diagnostic test results (i.s, spinal CT/MRI, etc) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:04:46
User closed query 'PV Query: Please confirm the treatment dates in the narrative, as the event occurred in October, but treatment dates are reported as in September.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:04:39
Query 'PV Query: The subject was treated with antibiotics. Please provide the indication.' answered with 'UNKNOWN UNTILL MEDCIAL RECORDS RECEIVED. PATIENT IS UNCLEAR ON DETAILS.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 20:06:09
Query 'PV Query: Please provide results of spinal tap.' answered with 'UNKNOWN UNTILL MEDCIAL RECORDS RECEIVED. PATIENT IS UNCLEAR ON DETAILS.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 20:06:04
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 'UNKNOWN UNTILL MEDCIAL RECORDS RECEIVED. RECORDS REQUESTED 10/19 AND AGAIN 10/30/20.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 20:06:00
Query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' answered with 'UNKNOWN UNTILL MEDCIAL RECORDS RECEIVED. PATIENT IS UNCLEAR ON DETAILS.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 20:05:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide diagnostic test results (i.s, spinal CT/MRI, etc) performed in evaluation of the event.' answered with 'UNKNOWN UNTILL MEDCIAL RECORDS RECEIVED. PATIENT IS UNCLEAR ON DETAILS.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 20:04:31
Query 'PV Query: Please confirm the treatment dates in the narrative, as the event occurred in October, but treatment dates are reported as in September.' answered with 'CORRECTED' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 20:04:15
Query 'Per DM CLR: SAE narrative indicates OXYCODONE, AN ANTIBIOTIC, A MUSCLE RELAXANT AND TYLENOL WERE PRESCRIBED, AND MORPHONE GIVEN VIA IV FLUIDS were given. However, there are no corresponding ConMed record to match these information. Please update to record these medications as appropriate. Otherwise, clarify.' answered with 'ADDED' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:04:07
Query 'Per DM CLR: SAE Narrative indicates that the subject underwent 3 Spinal taps and an E. Coli test. However, there are no corresponding Concomitant Procedure record that match this information. Please update to record the procedure as appropriate. Otherwise, clarify.' answered with 'ADDED' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:04:02
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 20:00:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PER PATIENT REPORT OVER PHONE ON 19OCT20 AT 13:22, ON 09OCT20 PATIENT HAD SYMPTOMS OF SEVERE NECK/BACK PAIN STARTING WITH NO KNOWN TRIGGER/INCIDENT. WIFE DROVE PATIENT TO ER AND PATIENT WAS HOSPITALIZED FOR 5 NIGHTS. PER PATIENT, 3 SPINAL TAPS WERE DONE, AND AN ECOLI AND COVID TEST PERFORMED, AND ALL FINDINGS WERE NEGATIVE. PER PATIENT, OXYCODONE, AN ANTIBIOTIC, A MUSCLE RELAXANT AND TYLENOL WERE PRESCRIBED, AND MORPHONE GIVEN VIA IV FLUIDS. PATIENT WAS ON IV FLUIDS 10/9-10/14. PATIENT DOES RECALL ALL MEDICATION DETAILS. PATIENT FEELS MUCH IMPROVED AND LAST DOSE OF ANTIBIOTICS AND PAIN MEDICATION WAS 10/16/2020. MEDICAL RECORDS WILL BE REQUESTED FOR MORE DETAILS.' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:00:37
	(b) (4), (b) (6)	06 Nov 2020 19:15:48
User opened query 'PV Query: The subject was treated with antibiotics. Please provide the indication.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 00:20:56
User opened query 'PV Query: Please provide results of spinal tap.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 00:20:47
User opened query 'PV Query: It was reported E. coli test was performed. Please specify test (i.e. urinary culture, etc)' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 00:20:37
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)	30 Oct 2020 00:17:48
User opened query 'PV Query: Please provide diagnostic test results (i.s, spinal CT/MRI, etc) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 00:16:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm the treatment dates in the narrative, as the event occurred in October, but treatment dates are reported as in September.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 00:10:33
User opened query 'Per DM CLR: SAE narrative indicates OXYCODONE, AN ANTIBIOTIC, A MUSCLE RELAXANT AND TYLENOL WERE PRESCRIBED, AND MORPHONE GIVEN VIA IV FLUIDS were given. However, there are no corresponding ConMed record to match these information. Please update to record these medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 00:05:12
User opened query 'Per DM CLR: SAE Narrative indicates that the subject underwent 3 Spinal taps and an E. Coli test. However, there are no corresponding Concomitant Procedure record that match this information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 00:04:58
User entered 'Per patient report over phone on 10/19/20 at 13:22, on 10/9/20 patient had symptoms of severe neck/back pain starting with no known trigger/incident. Wife drove patient to ER and patient was hospitalized for 5 nights. Per patient, 3 spinal taps were done, and an ecoli and COVID test performed, and all findings were negative. Per patient, oxycodone, an antibiotic, a muscle relaxant and Tylenol were prescribed, and morphine given via IV fluids. Patient was on IV fluids 9/10-9/14. Patient does recall all medication details. Patient feels much improved and last dose of antibiotics and pain medication was 10/16/2020. Medical records will be requested for more details.'	(b) (4), (b) (6)	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:29:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 21:59:37

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 20:09:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 20:09:20
Data point term sent to Coder	System	07 Nov 2020 20:08:41
User entered 'NECK PAIN'	(b) (4), (b) (6) (b) (4)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Nov 2020 20:44:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Nov 2020 20:44:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:44:30
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Nov 2020 20:08:39
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAD AN SAE OF SEVER NECK PAIN WITH HOSPITALIZATION 10/9-10/14/20, BUT CONDITION GREATLY IMPROVED ON 10/14/20 AND PATIENT WAS RELEASED FROM HOSPITAL. NECK PAIN IS STILL ONGOING AND PATIENT STILL TAAKING TYLENOL AND OXYCODOINE AS NEEDED, BUT FULLY FUNCTIONAL.'	(b) (4), (b) (6) [REDACTED]	07 Nov 2020 20:08:39

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Nov 2020 20:44:30

US3462091

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:29:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Nov 2020 20:08:39

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:00:25
User closed query 'Per ETRTR: According to SAE "Neck Pain" page, Concomitant Procedure was completed. Please complete data entry within Concomitant Procedures pages as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:03:03
User closed query 'Per ETRTR: Please add Medication dosed details for SAE "Neck Pain", thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:03:02
Query 'Per ETRTR: According to SAE "Neck Pain" page, Concomitant Procedure was completed. Please complete data entry within Concomitant Procedures pages as applicable, thanks.' answered with 'ADDED' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 20:45:14
Query 'Per ETRTR: Please add Medication dosed details for SAE "Neck Pain", thanks.' answered with 'ADDED' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 20:45:12
User opened query 'Per ETRTR: According to SAE "Neck Pain" page, Concomitant Procedure was completed. Please complete data entry within Concomitant Procedures pages as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:26:45
User opened query 'Per ETRTR: Please add Medication dosed details for SAE "Neck Pain", thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:25:00
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 22:26:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 22:26:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 22:26:53
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 22:26:49
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 22:26:49

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:06:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:06:30
Data point term sent to Coder	System	20 Oct 2020 00:00:24
Data point term sent to Coder	System	19 Oct 2020 23:59:20
User entered 'PREDNISONE'	(b) (4), (b) (6) (b) (4) (b) (4)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'CHRONIC OBSTRUCTIVE PULMNARY DISEASE EXACERBATION' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 23:59:48
User entered 'CHRONIC OBSTRUCTIVE PULMNARY DISEASE'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '24 Jun 2020'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Jun 2020'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 23:58:46

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 05:06:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 05:06:29
Data point term sent to Coder	System	20 Oct 2020 00:01:24
User entered 'PREDNISONE'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'CHRONIC OBSTRUCTIVE PULMINARY DISEASE EXACERBATION'	(b) (4), (b) (6) [REDACTED] [REDACTED]	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '27 Jun 2020'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Jun 2020'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:01:20

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
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)	20 Oct 2020 00:03:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:03:26
Data point term sent to Coder	System	20 Oct 2020 00:02:25
User entered 'METFORMIN'	(b) (4), (b) (6) (b) (4) (b) (4)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'TYPE II DIABETES'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2000'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:02:15

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:05:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:05:28
Data point term sent to Coder	System	20 Oct 2020 00:04:28
User entered 'LOSARTAN'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'CONGESTIVE HEART FAILURE'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:03:30

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
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)	20 Oct 2020 04:28:26
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 Oct 2020 04:28:26
Data point term sent to Coder	System	20 Oct 2020 00:04:29
User entered 'ATORVASTATIN'	(b) (4), (b) (6) (b) (4) (b) (4)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:06:28
User entered 'CHRONIC HEART FAILURE'	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:04:17

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: TORASEMIDE, PRODUCTSYNONYM: TORSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:07:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:07:27
Data point term sent to Coder	System	20 Oct 2020 00:05:29
User entered 'TORSEMIDE'	(b) (4), (b) (6) 	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:23:46
User entered 'BILATERAL LEG EDEMA'	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:05:13

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:07:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:07:27
Data point term sent to Coder	System	20 Oct 2020 00:06:31
User entered 'POTASSIUM'	(b) (4), (b) (6) (b) (4)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'SUPPLEMENT'	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:50:58
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:05:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
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)	20 Oct 2020 00:08:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:08:27
Data point term sent to Coder	System	20 Oct 2020 00:07:32
User entered 'ASPIRIN'	(b) (4), (b) (6) 	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:45:52
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'CARDIAC PROPHYLAXIS'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:06:50

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: ARFORMOTEROL TARTRATE, PRODUCTSYNONYM: BROVANA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:09:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:09:28
Data point term sent to Coder	System	20 Oct 2020 00:08:33
User entered 'BROVANA'	(b) (4), (b) (6) 	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'CHRONIC OBSTRUCTIVE PULMINARY DISEASE'	(b) (4), (b) (6) [REDACTED] [REDACTED]	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'NEBULIZER'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN May 2020'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:08:14

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 05:04:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 05:04:38
Data point term sent to Coder	System	20 Oct 2020 00:09:33
User entered 'QVAR'	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'CHRONIC OBSTRUCTIVE PULMINARY DISEASE'	(b) (4), (b) (6) [REDACTED] [REDACTED]	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). User entered '2'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 07:01:10 20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:01:04
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:00:59
User entered 'puff (PUFF)'	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:09:09

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: OLODATEROL HYDROCHLORIDE;Tiotropium Bromide MONOHYDRATE, PRODUCTSYNONYM: STIOLTO RESPIMAT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:57:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:57:32
Data point term sent to Coder	System	20 Oct 2020 00:10:34
User entered 'STIOLTO'	(b) (4), (b) (6) (b) (4) (b) (4)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'CHRONIC OBSTRUCTIVE PULMINARY DISEASE'	(b) (4), (b) (6) [REDACTED] [REDACTED]	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'puff (PUFF)'	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:10:23

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 00:13:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 00:13:28
Data point term sent to Coder	System	20 Oct 2020 00:12:35
User entered 'JARDIANCE'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	23 Nov 2020 03:52:10
User entered 'CHRONIC HEARY FAILURE'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
User entered '10 Jul 2020'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 00:12:04

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:16:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:16:29
Data point term sent to Coder	System	07 Nov 2020 20:14:42
User entered 'morphine'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'neck pain'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered '1'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'dose unknown'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'other (OTHER)'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'continuous'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered '9 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered '10 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:50
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:14:35

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:17:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:17:29
Data point term sent to Coder	System	07 Nov 2020 20:20:45
User entered 'oxycodone'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'neck pain'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered '1'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'QIDPRN'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered '11 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered '16 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:47
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:19:58

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 20:23:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 20:23:20
Data point term sent to Coder	System	07 Nov 2020 20:21:46
User entered 'TYLENOL'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'NECK PAIN'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered '650'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	07 Nov 2020 20:21:28
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:21:28
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	07 Nov 2020 20:21:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'QIDPRN'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered '9 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:43
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:21:28
User entered '1'	System	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:21:28
User entered '1'	System	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:21:28
User entered '804 (804)'	System	07 Nov 2020 20:21:07

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User opened query 'Please clarify what the name of this Muscle Relaxant is. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:04:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, PRODUCT: MUSCLE RELAXANTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:16:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:16:30
Data point term sent to Coder	System	07 Nov 2020 20:24:47
Data point term sent to Coder	System	07 Nov 2020 20:23:47
User entered 'MUSCLE RELAXANT'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'NECK PAIN'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered '1'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'as needed (PRN)'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:23:55
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User closed query 'Route of administration is Other, however Other, specify is missing. Please provide.' (Site from System).	System	07 Nov 2020 20:23:55
User opened query 'Route of administration is Other, however Other, specify is missing. Please provide.' (Site from System).	System	07 Nov 2020 20:23:11
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered '9 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:39
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:23:11

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:07:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:07:29
Data point term sent to Coder	System	07 Nov 2020 20:26:49
User entered 'ANTIBIOTIC'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User opened query 'Per source Con Med Log, indication is noted as Neck Pain. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:02:51
User entered 'UNKNOWN'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User opened query 'Per CDM: Per CCGs, if Dose per administration is unknown, then per the CCGs, it should be recorded as UNK. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 12:17:00
User entered 'UNKNOWN'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'UNKNOWN. WAITING FOR MEDICAL RECORDS.'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered '09 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).		07 Nov 2020 20:26:53
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:26:53
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).		07 Nov 2020 20:26:33
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:06:35
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:29:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 20:26:33

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:29:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Nov 2020 20:08:53

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:09:40

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'SPINAL TAP'	(b) (4), (b) (6)	07 Nov 2020 20:09:40

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	07 Nov 2020 20:09:40

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:29:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:09:40

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 20:11:11
User entered '10 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:10:02

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'SPINAL TAP'	(b) (4), (b) (6)	07 Nov 2020 20:10:02

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	07 Nov 2020 20:10:02

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:29:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:10:02

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:10:55

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'SPINAL TAP'	(b) (4), (b) (6)	07 Nov 2020 20:10:55

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	07 Nov 2020 20:10:55

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:29:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:10:55

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:10:43

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'NASAL SWAB'	(b) (4), (b) (6)	07 Nov 2020 20:10:43

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	07 Nov 2020 20:10:43

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:29:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:10:43

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:11:42

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'ECOLI TEST'	(b) (4), (b) (6)	07 Nov 2020 20:11:42

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	07 Nov 2020 20:11:42

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 09:29:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:11:42

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:12:07

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Electrocardiogram'	(b) (4), (b) (6)	07 Nov 2020 20:12:07

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	07 Nov 2020 20:12:07

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 09:29:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:12:07

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	07 Nov 2020 20:12:38

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 09:29:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'IV fluids'	(b) (4), (b) (6)	07 Nov 2020 20:12:38

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 09:29:21

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	07 Nov 2020 20:12:38

US3462091

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 26 Nov 2020 09:29:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Nov 2020 20:12:38

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'USA-US093-2020-MRNA-1273-P301000007'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Edward'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Kerwin'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:05:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
User entered 'US'	System	20 Oct 2020 16:47:10

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Nov 2020 11:05:46
User entered '1'	System	20 Oct 2020 16:47:10

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'USA-US093-2020-MRNA-1273-P301000007'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Edward'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Kerwin'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:05:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
User entered 'US'	System	20 Oct 2020 16:47:10

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Nov 2020 11:05:46
User entered '1'	System	20 Oct 2020 16:47:10

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:29:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
User entered '20/Oct/2020 16:47'	System	20 Oct 2020 16:47:10

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:29:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:05:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 16:47:10

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'USA-US093-2020-MRNA-1273-P301000007'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Yes (Y)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'No (N)'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Edward'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 16:47:01
User entered 'Kerwin'	System	20 Oct 2020 16:46:40

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:05:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:13:04
User entered 'US'	System	20 Oct 2020 16:47:10

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 09:29:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Nov 2020 11:05:46
User entered '1'	System	20 Oct 2020 16:47:10

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:29:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '09/Nov/2020 06:05'	System	09 Nov 2020 11:05:46

US3462091

Folder: SAE USA-US093-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:29:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 11:05:46