

US3812098 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:20:44

All time stamps listed in this document are displayed in GMT

US3812098

Form: Participant Creation

Generated On: 26 Nov 2020 11:20:44

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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 11:20:44

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
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 11:20:44

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 11:20:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:20:44

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

Condition	VASECTOMY
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)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

Condition	(R) INGUINAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

Condition	(R) INGUINAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

Condition	CRANIOFACIAL SEPARATION
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

Condition	CRANIOFACIAL RECONSTRUCTION
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

Condition	ANOSMIA
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

Condition	DEPENDENCY OF RIGHT EYE PROSTHETIC
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

Condition	HISTORY OF MOTOR VEHICLE ACCIDENT
Start date (dd MMM yyyy)	03 NOV 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	03 NOV 1985
Stop date completely unknown	False
Start Month and Year (derived)	NOV 1985
Start Year (derived)	1985
Stop Month and Year (derived)	NOV 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

Condition	SHRIMP ALLERGY
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 (11)

Generated On: 26 Nov 2020 11:20:44

Condition	SULFA ALLERGY
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 (12)

Generated On: 26 Nov 2020 11:20:44

Condition	ALCOHOL USE-16 OZ OF WINE/DAY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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>)	08:07 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 08:07
Height (<i>xxx.x</i>)	68.7 in
Weight (<i>xxx.x</i>)	162.6 lb
BMI (<i>xxx.x</i>)	24.27264 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

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 11:20:44

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

BABYSITS

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	True
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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 11:20:44

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

What was the participant's randomization number? 185352

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 11:20:44

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 11:20:44

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)	08:07 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 08:07
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 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 11:20:44

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)	10:19 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:19
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 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: Physical Examination

Generated On: 26 Nov 2020 11:20:44

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 11:20:44

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) 09:47 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 09:47

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 11:20:44

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

10 AUG 2020

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

09:20 (24 HR)

Collection date and time (derived)

10 AUG 2020 09:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:20:44

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	09:25	10 AUG 2020 09:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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 11:20:44

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

97.9 °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

10 AUG 2020 10:24

PC Open Date & Time

10 AUG 2020 10:07

PC Close Date & Time

10 AUG 2020 12:37

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 99.5 °F

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

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

PC Time Stamp	10 AUG 2020 17:58
PC Open Date & Time	10 AUG 2020 13:32
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 11:20:44

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

98.4 °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

11 AUG 2020 16:58

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 11:20:44

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

99.4 °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

12 AUG 2020 16:39

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 11:20:44

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

98.5 °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 AUG 2020 15:14

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

14 AUG 2020 15:52

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

15 AUG 2020 18:41

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

98.0 °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

16 AUG 2020 19:07

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 10:25

PC Open Date & Time

10 AUG 2020 10:07

PC Close Date & Time

10 AUG 2020 12:37

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 18:00

PC Open Date & Time

10 AUG 2020 13:32

PC Close Date & Time

11 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 2

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

11 AUG 2020 16:59

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 16:40

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 15:14

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 15:52

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 18:41

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 19:08

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 10:27
PC Open Date & Time	10 AUG 2020 10:07
PC Close Date & Time	10 AUG 2020 12:37

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 18:01
PC Open Date & Time	10 AUG 2020 13:32
PC Close Date & Time	11 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	12 AUG 2020 16:41
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	13 AUG 2020 15:15
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	14 AUG 2020 15:53
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	15 AUG 2020 18:42
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	16 AUG 2020 19:08
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3812098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

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

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812098

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812098

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812098

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	08:08 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 08:08
Temperature (xxx.x)	97.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:08
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3812098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

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.

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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 SEP 2020
What was the treatment time? (00:00-23:59)	08:37 (24 HR)
Treatment Date and Time (derived)	10 SEP 2020 08:37
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

US3812098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	10 SEP 2020
Collection time (<i>00:00-23:59</i>)	08:24 (24 HR)
Collection date and time (derived)	10 SEP 2020 08:24

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:20:44

Collection date (<i>dd MMM yyyy</i>)			10 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	08:27	10 SEP 2020 08:27
Nasopharyngeal Swab 2	No		

US3812098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

10 SEP 2020 09:12

PC Open Date & Time

10 SEP 2020 08:57

PC Close Date & Time

10 SEP 2020 11:27

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 99.8 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 10 SEP 2020 17:02

PC Open Date & Time 10 SEP 2020 12:22

PC Close Date & Time 11 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

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	98.1 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False
PC Time Stamp	11 SEP 2020 15:13
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

98.4 °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

13 SEP 2020 10:08

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

98.9 °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

13 SEP 2020 14:42

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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 SEP 2020 18:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

15 SEP 2020 18:38

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

98.3 °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

16 SEP 2020 17:50

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 SEP 2020 09:13

PC Open Date & Time

10 SEP 2020 08:57

PC Close Date & Time

10 SEP 2020 11:27

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 SEP 2020 17:04

PC Open Date & Time

10 SEP 2020 12:22

PC Close Date & Time

11 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 SEP 2020 15:14

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

13 SEP 2020 10:09

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 SEP 2020 14:42

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 SEP 2020 18:21

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 SEP 2020 18:39

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 SEP 2020 17:50

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 09:14
PC Open Date & Time	10 SEP 2020 08:57
PC Close Date & Time	10 SEP 2020 11:27

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 17:05
PC Open Date & Time	10 SEP 2020 12:22
PC Close Date & Time	11 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	13 SEP 2020 10:09
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	13 SEP 2020 14:43
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	14 SEP 2020 18:21
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	15 SEP 2020 18:40
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	16 SEP 2020 17:51
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3812098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812098

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812098

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812098

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	09 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:50 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 09:50
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

US3812098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

09 OCT 2020

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

10:20 (24 HR)

Collection date and time (derived)

09 OCT 2020 10:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐
Date and time of submission	14 OCT 2020 08:44:39
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

20 OCT 2020 12:13:29

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

27 OCT 2020 07:26:57

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

11 NOV 2020 08:14:43

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

17 NOV 2020 12:54:55

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

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10 JAN 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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 FEB 2021 00:01

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07 FEB 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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28 FEB 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 MAR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 MAR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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 MAR 2021 00:01

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21 MAR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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11 APR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

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12 SEP 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

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19 SEP 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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19 JAN 2022 00:01

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23 JAN 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

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

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

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

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

Date and time of submission

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 APR 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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17 APR 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

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29 MAY 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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12 JUN 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

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03 JUL 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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10 JUL 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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 JUL 2022 00:01

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24 JUL 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

US3812098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812098

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812098

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812098

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:20:44

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

US3812098

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:20:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

AEID	USA-US111-2020-MRNA-1273-P30 1000005
Adverse event	PROSTATE CANCER
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)	28 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	346 of 1921

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	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	

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

14 OCT 2020 AT 10:30 AM-
SUBJECT CALLED TODAY AND
REPORTED ELEVATED PSA IS
NOW A DIAGNOSIS OF
PROSTATE CANCER. PSA LEVEL
COLLECTED ON AUG 03, 2020
WAS 6.0 NG/ML. SUBJECT IS
SCHEDULED FOR A
PROSTATECTOMY ON 13 JAN
2021. SUBJECT DENIES ANY
OTHER CHANGES IN
TREATMENT OR MEDICATIONS
AT THIS TIME.

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)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

AEID

Adverse event

BILATERAL HIP 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)

24 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

v6.020 DTW (1102)

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US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

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 _____	
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)	_____

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

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

v6.020 DTW (1102)

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US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

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 _____	
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)	_____

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

AEID	
Adverse event	WORSENING LEFT CATARACT
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)	15 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

v6.020 DTW (1102)

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US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

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	False
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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:20:44

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

Yes ☒

No ☐

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

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
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 ☐

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	CEFTRIAXONE
Prophylaxis	Yes ☒ No ☐
Indication	PROSTATE CANCER
Dose per administration	2.4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		02 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	☐

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		11 SEP 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	☒

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 24 SEP 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	☒

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	BILATERAL HIP PAIN AND NECK PAIN
Dose per administration	325
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 ☐

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 24 SEP 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	☒

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	BILATERAL HIP PAIN
Dose per administration	50
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 ☐

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

	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)		04 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 NOV 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	PNEUMOVAX
Prophylaxis	Yes ☐ No ☒
Indication	IMMUNIZATION
Dose per administration	0.5
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 ☒

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

	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)		04 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		04 NOV 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	☐

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:20:44

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:20:44

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 OCT 2020	BIOPSY OF PROSTATE	Adverse Event	
15 OCT 2020	LEFT CATARACT REMOVAL	Adverse Event	

US3812098

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:20:44

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

US3812098

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

SAEID	USA-US111-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:20:44

SAEID	USA-US111-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/OCT/2020 12:47
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

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:20:44

SAEID	USA-US111-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/OCT/2020 20:21
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.	True

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:20:44

SAEID	USA-US111-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 20:27
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

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:20:44

SAEID	USA-US111-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	LARKIN
Investigator's Last Name	WADSWORTH
Site Address: Street	711 OLD BALLAS RD SUITE 105
Site Address: City	ST LOUIS
Site Address: State	
Site Address: Postal Code	63141
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3812098 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812098

Form: Participant Creation

Generated On: 26 Nov 2020 11:20:44

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3812098'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 13:59:15

US3812098

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:03:45

US3812098

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 13:59:16

US3812098

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:03:45

US3812098

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	10 Aug 2020 15:03:45

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 13:59:17

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Age](#)

Audit	User	Time (GMT)
User entered '67'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '67'	System	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[White](#)

Audit	User	Time (GMT)
User entered '1'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:21

US3812098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2020'	System	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[Protocol Version](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 15:04:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 15:04:40
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:40
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 15:04:30
User entered empty.	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:04:30

US3812098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 13:59:16

US3812098

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:05:21

US3812098

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:05:21

US3812098

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:20:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:46:59

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:48:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	11 Aug 2020 18:48:17
Data point term sent to Coder	System	11 Aug 2020 18:48:01
User entered 'VASECTOMY'	Breanna Galibert (b) (4)	11 Aug 2020 18:47:18
	(b) (4)	

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:47:18

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:47:18

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:39:02
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. Update eCRF as appropriate. ' answered with 'corrected to include stop date' (Site from DM).	Anya Penly (b) (4)	21 Oct 2020 14:43:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 14:42:52
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 18:21:44
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Aug 2020 18:47:18

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'un UNK 2008' reason for change:	Anya Penly (b) (4)	21 Oct 2020 14:42:52
Data Entry Error	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	11 Aug 2020 18:47:18
	(b) (4)	

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:47:18

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	11 Aug 2020 18:47:18

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2008'	System	11 Aug 2020 18:47:18

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	21 Oct 2020 14:42:52
User entered empty.	System	11 Aug 2020 18:47:18

US3812098

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2008'	System	21 Oct 2020 14:42:52
User entered empty.	System	11 Aug 2020 18:47:18

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Right inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:58:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:58:14
Data point term sent to Coder	System	11 Aug 2020 18:48:04
User entered '(R) INGUINAL HERNIA'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2009'	System	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2009'	System	11 Aug 2020 18:48:02

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:58:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:58:14
Data point term sent to Coder	System	11 Aug 2020 18:49:07
User entered '(R) INGUINAL HERNIA REPAIR'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2009'	System	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2009'	System	11 Aug 2020 18:48:32

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Craniofacial fracture, LLT: Craniofacial dysjunction fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:36:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:36:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Skull fracture, LLT: Skull fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:09:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:09:45
Data point term sent to Coder	System	05 Nov 2020 15:24:59
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 15:24:13
User entered 'CRANIOFACIAL SEPARATION' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 15:24:13
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of skull congenital, PT: Craniofacial deformity, LLT: Craniofacial deformity - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:13:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:13:15
Data point term sent to Coder	System	11 Aug 2020 18:49:10
User entered 'FACIAL CRANIAL SEPERATION'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1985'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1985'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1985'	System	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1985'	System	11 Aug 2020 18:48:58

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Skull and brain therapeutic procedures, PT: Cranioplasty, LLT: Cranioplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:57:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:57:45
Data point term sent to Coder	System	05 Nov 2020 15:24:59
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 15:24:34
User entered 'CRANIOFACIAL RECONSTRUCTION' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	05 Nov 2020 15:24:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Facial therapeutic procedures, PT: Facial operation, LLT: Facial operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:10:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:10:24
Data point term sent to Coder	System	11 Aug 2020 18:50:11
User entered 'FACIAL CRANIAL REPAIR'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:49:18

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1985'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:49:18

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:49:18

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:49:18

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1985'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:49:18

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:49:18

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	11 Aug 2020 18:49:18

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1985'	System	11 Aug 2020 18:49:18

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	11 Aug 2020 18:49:18

US3812098

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1985'	System	11 Aug 2020 18:49:18

US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Olfactory nerve disorders, PT: Anosmia, LLT: Anosmia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:52:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:52:17
Data point term sent to Coder	System	11 Aug 2020 18:51:14
User entered 'ANOSMIA'	Breanna Galibert (b) (4)	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1985'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1985'	System	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:50:25

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Eye prosthesis user, LLT: Eye prosthesis user - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:53:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:53:28
Data point term sent to Coder	System	21 Oct 2020 14:49:34
Coding entries removed.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:48:42
User entered 'Dependency of right eye prosthetic' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:48:42
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Eye prosthesis user, LLT: Eye prosthesis user - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:59:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:59:16
Data point term sent to Coder	System	11 Aug 2020 18:51:15
User entered '(R) PROSTHETIC EYE'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 1985'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:39:55
Query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' answered with 'clarified term to reflect ongoing condition, per Investigator' (Site from DM).	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:49:04
User opened query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 18:22:26
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1985'	System	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:50:51

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:13:00
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:50:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:50:52
Data point term sent to Coder	System	22 Sep 2020 17:44:55
Query 'Per MM, please expand the abbreviation.' answered with 'expanded per query' (Site from DM).	Anya Penly (b) (4) (b) (4)	22 Sep 2020 17:44:50
Coding entries removed.	Anya Penly (b) (4) (b) (4)	22 Sep 2020 17:44:42
User entered 'HISTORY OF motor vehicle accident' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	22 Sep 2020 17:44:42
User opened query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:27:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 12:54:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 12:54:31
Data point term sent to Coder	System	11 Aug 2020 18:52:17
User entered 'HISTORY OF MVA'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '03 Nov 1985'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '03 Nov 1985'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Nov 1985'	System	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1985'	System	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Nov 1985'	System	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1985'	System	11 Aug 2020 18:51:23

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

[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: Cataract (left) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:56:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:56:15
Data point term sent to Coder	System	11 Aug 2020 18:52:19
User entered '(L) CATARACT'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:46

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN Feb 2020'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:46

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:46

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:46

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:46

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:51:46

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	11 Aug 2020 18:51:46

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 18:51:46

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:51:46

US3812098

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:51:46

US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Shellfish allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:35:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:35:19
Data point term sent to Coder	System	11 Aug 2020 18:52:19
User entered 'SHRIMP ALLERGY'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2015'	System	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:52:11

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:54:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:54:16
Data point term sent to Coder	System	11 Aug 2020 18:53:20
User entered 'SULFA ALLERGY'	Breanna Galibert (b) (4)	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2015'	System	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:52:30

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:06:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:06:14
Data point term sent to Coder	System	11 Aug 2020 18:53:23
User entered 'ALCOHOL USE-16 OZ OF WINE/DAY'	Breanna Galibert (b) (4)	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2000'	System	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:53:08

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '08:07'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 08:07'	System	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '68.7' in	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41
DataPoint set to visible.	(b) (4) System	10 Aug 2020 15:05:21

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '162.6' lb	Breanna Galibert (b) (4)	11 Aug 2020 18:54:41
DataPoint set to visible.	(b) (4) System	10 Aug 2020 15:05:21

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '24.27264'	System	16 Sep 2020 23:49:37
User entered '24.3'	System	11 Aug 2020 18:54:41
DataPoint set to visible.	System	10 Aug 2020 15:05:21

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Aug 2020 18:54:41
DataPoint set to visible.	System	10 Aug 2020 15:05:21

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 18:54:41

US3812098

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:54:53

US3812098

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

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)	13 Sep 2020 18:34:33
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 14:06:11
User entered '10 Aug 2020'	Breanna Galibert (b) (4)	11 Aug 2020 18:54:53

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Specify](#)

Audit	User	Time (GMT)
User entered 'BABYSITS'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:55:46

US3812098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:05:36

US3812098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Heather Cherniawski (b) (4)	10 Aug 2020 15:05:36

US3812098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:05:36

US3812098

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	10 Aug 2020 15:05:36

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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 14:19:30

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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 03:14:07
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:14:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 14:19:30
User entered '185352' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 14:19:30

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 14:19:30

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:06

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:06

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:06

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:06

US3812098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:06

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '08:07'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 08:07'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '13'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:27:43
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 18:58:28
User entered '10:19'	Breanna Galibert (b) (4)	11 Aug 2020 18:58:28
	(b) (4)	

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:19'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '15'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 18:58:28

US3812098

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:47

US3812098

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:47

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Heather Cherniawski (b) (4)	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '09:47'	Heather Cherniawski (b) (4)	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 09:47'	System	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski (b) (4)	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 15:07:32

US3812098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:22

US3812098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:22

US3812098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:20'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:22

US3812098

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 09:20'	System	11 Aug 2020 18:56:22

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:20:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:25'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Aug 2020 09:25'	System	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 18:56:44

US3812098

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	18 Aug 2020 18:27:26

US3812098

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 18:27:26

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:23:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '02038dfe-8704-4635-930b-ec3d64220815'	System	10 Aug 2020 15:24:59
User entered 'Yes (Y)'	System	10 Aug 2020 15:24:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:24:27', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '02038dfe-8704-4635-930b-ec3d64220815'	System	10 Aug 2020 15:24:59
User entered '97.9'	System	10 Aug 2020 15:24:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:24:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '02038dfe-8704-4635-930b-ec3d64220815'	System	10 Aug 2020 15:24:59
User entered 'No (N)'	System	10 Aug 2020 15:24:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:24:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '02038dfe-8704-4635-930b-ec3d64220815'	System	10 Aug 2020 15:24:59
User entered '10 Aug 2020 10:24'	System	10 Aug 2020 15:24:59

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:07'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:37'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:58:33', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '83ac1035-f2a9-4c8d-a9cd-59c217c324f1'	System	10 Aug 2020 22:59:02
User entered 'Yes (Y)'	System	10 Aug 2020 22:59:02

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:58:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '83ac1035-f2a9-4c8d-a9cd-59c217c324f1'	System	10 Aug 2020 22:59:02
User entered '99.5'	System	10 Aug 2020 22:59:02

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:58:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '83ac1035-f2a9-4c8d-a9cd-59c217c324f1'	System	10 Aug 2020 22:59:02
User entered 'No (N)'	System	10 Aug 2020 22:59:02

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:58:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '83ac1035-f2a9-4c8d-a9cd-59c217c324f1'	System	10 Aug 2020 22:59:02
User entered '10 Aug 2020 17:58'	System	10 Aug 2020 22:59:02

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 13:32'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 2'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:58:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5df582da-cea8-48f3-81b8-06eaa301e75e'	System	11 Aug 2020 21:59:01
User entered 'Yes (Y)'	System	11 Aug 2020 21:59:01

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:58:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5df582da-cea8-48f3-81b8-06eaa301e75e'	System	11 Aug 2020 21:59:01
User entered '98.4'	System	11 Aug 2020 21:59:01

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:58:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5df582da-cea8-48f3-81b8-06eaa301e75e'	System	11 Aug 2020 21:59:01
User entered 'No (N)'	System	11 Aug 2020 21:59:01

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:58:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '5df582da-cea8-48f3-81b8-06eaa301e75e' User entered '11 Aug 2020 16:58'	System	11 Aug 2020 21:59:01
	System	11 Aug 2020 21:59:01

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 3'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:39:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ad046827-ae67-4557-b502-b38a904f73cd'	System	12 Aug 2020 21:40:06
User entered 'Yes (Y)'	System	12 Aug 2020 21:40:06

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:39:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ad046827-ae67-4557-b502-b38a904f73cd'	System	12 Aug 2020 21:40:06
User entered '99.4'	System	12 Aug 2020 21:40:06

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:39:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ad046827-ae67-4557-b502-b38a904f73cd'	System	12 Aug 2020 21:40:06
User entered 'No (N)'	System	12 Aug 2020 21:40:06

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:39:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ad046827-ae67-4557-b502-b38a904f73cd'	System	12 Aug 2020 21:40:06
User entered '12 Aug 2020 16:39'	System	12 Aug 2020 21:40:06

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 4'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:13:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ec81e64b-79a2-4744-ad07-a5c73cc00802'	System	13 Aug 2020 20:14:21
User entered 'Yes (Y)'	System	13 Aug 2020 20:14:21

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:13:50', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ec81e64b-79a2-4744-ad07-a5c73cc00802'	System	13 Aug 2020 20:14:21
User entered '98.5'	System	13 Aug 2020 20:14:21

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:13:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ec81e64b-79a2-4744-ad07-a5c73cc00802'	System	13 Aug 2020 20:14:21
User entered 'No (N)'	System	13 Aug 2020 20:14:21

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:01', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ec81e64b-79a2-4744-ad07-a5c73cc00802'	System	13 Aug 2020 20:14:21
User entered '13 Aug 2020 15:14'	System	13 Aug 2020 20:14:21

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 5'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:51:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2f34a237-7b52-4048-8988-814363a68b68'	System	14 Aug 2020 20:52:26
User entered 'Yes (Y)'	System	14 Aug 2020 20:52:26

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:51:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2f34a237-7b52-4048-8988-814363a68b68'	System	14 Aug 2020 20:52:26
User entered '98.6'	System	14 Aug 2020 20:52:26

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2f34a237-7b52-4048-8988-814363a68b68'	System	14 Aug 2020 20:52:26
User entered 'No (N)'	System	14 Aug 2020 20:52:26

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2f34a237-7b52-4048-8988-814363a68b68'	System	14 Aug 2020 20:52:26
User entered '14 Aug 2020 15:52'	System	14 Aug 2020 20:52:26

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 6'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:40:54', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e45edfee-a0e3-43b8-acaf-d80444f98e51'	System	17 Aug 2020 00:04:52
User entered 'Yes (Y)'	System	17 Aug 2020 00:04:52

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e45edfee-a0e3-43b8-acaf-d80444f98e51'	System	17 Aug 2020 00:04:52
User entered '98.6'	System	17 Aug 2020 00:04:52

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:04', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e45edfee-a0e3-43b8-acaf-d80444f98e51'	System	17 Aug 2020 00:04:52
User entered 'No (N)'	System	17 Aug 2020 00:04:52

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:10', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e45edfee-a0e3-43b8-acaf-d80444f98e51'	System	17 Aug 2020 00:04:52
User entered '15 Aug 2020 18:41'	System	17 Aug 2020 00:04:52

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 7'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:06:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '17a182cd-3afb-4fb9-a586-63eb7e93ee93'	System	17 Aug 2020 00:07:39
User entered 'Yes (Y)'	System	17 Aug 2020 00:07:39

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:06:50', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '17a182cd-3afb-4fb9-a586-63eb7e93ee93'	System	17 Aug 2020 00:07:39
User entered '98.0'	System	17 Aug 2020 00:07:39

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '17a182cd-3afb-4fb9-a586-63eb7e93ee93'	System	17 Aug 2020 00:07:39
User entered 'No (N)'	System	17 Aug 2020 00:07:39

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '17a182cd-3afb-4fb9-a586-63eb7e93ee93'	System	17 Aug 2020 00:07:39
User entered '16 Aug 2020 19:07'	System	17 Aug 2020 00:07:39

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:25:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9ae0ea8e-2c95-4db6-9df2-3a11ea49d625'	System	10 Aug 2020 15:26:01
User entered 'None (1)'	System	10 Aug 2020 15:26:01

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:25:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9ae0ea8e-2c95-4db6-9df2-3a11ea49d625'	System	10 Aug 2020 15:26:01
User entered 'No (N)'	System	10 Aug 2020 15:26:01

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:25:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9ae0ea8e-2c95-4db6-9df2-3a11ea49d625'	System	10 Aug 2020 15:26:01
User entered 'No (N)'	System	10 Aug 2020 15:26:01

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:25:49', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9ae0ea8e-2c95-4db6-9df2-3a11ea49d625'	System	10 Aug 2020 15:26:01
User entered 'None (1)'	System	10 Aug 2020 15:26:01

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:25:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9ae0ea8e-2c95-4db6-9df2-3a11ea49d625' User entered '10 Aug 2020 10:25'	System	10 Aug 2020 15:26:01
	System	10 Aug 2020 15:26:01

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:07'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:37'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:59:17', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '59aaaf74-e7e1-48aa-9607-ab5eb33e6071'	System	10 Aug 2020 23:00:11
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 23:00:11

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:59:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '59aaaf74-e7e1-48aa-9607-ab5eb33e6071'	System	10 Aug 2020 23:00:11
User entered 'No (N)'	System	10 Aug 2020 23:00:11

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:59:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '59aaaf74-e7e1-48aa-9607-ab5eb33e6071'	System	10 Aug 2020 23:00:11
User entered 'No (N)'	System	10 Aug 2020 23:00:11

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T17:59:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '59aaaf74-e7e1-48aa-9607-ab5eb33e6071'	System	10 Aug 2020 23:00:11
User entered 'None (1)'	System	10 Aug 2020 23:00:11

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:10', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '59aaaf74-e7e1-48aa-9607-ab5eb33e6071'	System	10 Aug 2020 23:00:11
User entered '10 Aug 2020 18:00'	System	10 Aug 2020 23:00:11

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 13:32'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 2'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:59:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '62f308b1-5ed3-4847-92a8-c31bf96e17b4'	System	11 Aug 2020 21:59:50
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 21:59:50

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:59:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '62f308b1-5ed3-4847-92a8-c31bf96e17b4'	System	11 Aug 2020 21:59:50
User entered 'No (N)'	System	11 Aug 2020 21:59:50

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:59:27', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '62f308b1-5ed3-4847-92a8-c31bf96e17b4'	System	11 Aug 2020 21:59:50
User entered 'No (N)'	System	11 Aug 2020 21:59:50

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:59:38', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '62f308b1-5ed3-4847-92a8-c31bf96e17b4'	System	11 Aug 2020 21:59:50
User entered 'None (1)'	System	11 Aug 2020 21:59:50

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T16:59:49', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '62f308b1-5ed3-4847-92a8-c31bf96e17b4'	System	11 Aug 2020 21:59:50
User entered '11 Aug 2020 16:59'	System	11 Aug 2020 21:59:50

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 3'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7725581f-cc0b-4462-825e-21e5b5f5878b'	System	12 Aug 2020 21:41:07
User entered 'None (1)'	System	12 Aug 2020 21:41:07

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:11', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7725581f-cc0b-4462-825e-21e5b5f5878b'	System	12 Aug 2020 21:41:07
User entered 'No (N)'	System	12 Aug 2020 21:41:07

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:15', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7725581f-cc0b-4462-825e-21e5b5f5878b'	System	12 Aug 2020 21:41:07
User entered 'No (N)'	System	12 Aug 2020 21:41:07

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:30', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7725581f-cc0b-4462-825e-21e5b5f5878b'	System	12 Aug 2020 21:41:07
User entered 'None (1)'	System	12 Aug 2020 21:41:07

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7725581f-cc0b-4462-825e-21e5b5f5878b'	System	12 Aug 2020 21:41:07
User entered '12 Aug 2020 16:40'	System	12 Aug 2020 21:41:07

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 4'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee5187fc-9964-486b-9178-317d3a3c3521'	System	13 Aug 2020 20:14:31
User entered 'None (1)'	System	13 Aug 2020 20:14:31

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:11', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee5187fc-9964-486b-9178-317d3a3c3521'	System	13 Aug 2020 20:14:31
User entered 'No (N)'	System	13 Aug 2020 20:14:31

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:15', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee5187fc-9964-486b-9178-317d3a3c3521'	System	13 Aug 2020 20:14:31
User entered 'No (N)'	System	13 Aug 2020 20:14:31

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:19', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee5187fc-9964-486b-9178-317d3a3c3521'	System	13 Aug 2020 20:14:31
User entered 'None (1)'	System	13 Aug 2020 20:14:31

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee5187fc-9964-486b-9178-317d3a3c3521'	System	13 Aug 2020 20:14:31
User entered '13 Aug 2020 15:14'	System	13 Aug 2020 20:14:31

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 5'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e8951df1-e46f-4a39-bde6-3563ad76f560'	System	14 Aug 2020 20:53:02
User entered 'None (1)'	System	14 Aug 2020 20:53:02

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:36', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e8951df1-e46f-4a39-bde6-3563ad76f560'	System	14 Aug 2020 20:53:02
User entered 'No (N)'	System	14 Aug 2020 20:53:02

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e8951df1-e46f-4a39-bde6-3563ad76f560'	System	14 Aug 2020 20:53:02
User entered 'No (N)'	System	14 Aug 2020 20:53:02

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:46', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e8951df1-e46f-4a39-bde6-3563ad76f560'	System	14 Aug 2020 20:53:02
User entered 'None (1)'	System	14 Aug 2020 20:53:02

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:52:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e8951df1-e46f-4a39-bde6-3563ad76f560'	System	14 Aug 2020 20:53:02
User entered '14 Aug 2020 15:52'	System	14 Aug 2020 20:53:02

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 6'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8a5d35ff-44dd-4f3f-9281-f14d7b15acf6'	System	17 Aug 2020 00:04:54
User entered 'None (1)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:22', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8a5d35ff-44dd-4f3f-9281-f14d7b15acf6'	System	17 Aug 2020 00:04:54
User entered 'No (N)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8a5d35ff-44dd-4f3f-9281-f14d7b15acf6'	System	17 Aug 2020 00:04:54
User entered 'No (N)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8a5d35ff-44dd-4f3f-9281-f14d7b15acf6'	System	17 Aug 2020 00:04:54
User entered 'None (1)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '8a5d35ff-44dd-4f3f-9281-f14d7b15acf6'	System	17 Aug 2020 00:04:54
User entered '15 Aug 2020 18:41'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 7'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:44', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2c933b79-d6d2-4f9d-bbb7-7da546186b50'	System	17 Aug 2020 00:08:04
User entered 'None (1)'	System	17 Aug 2020 00:08:04

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2c933b79-d6d2-4f9d-bbb7-7da546186b50'	System	17 Aug 2020 00:08:04
User entered 'No (N)'	System	17 Aug 2020 00:08:04

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2c933b79-d6d2-4f9d-bbb7-7da546186b50'	System	17 Aug 2020 00:08:04
User entered 'No (N)'	System	17 Aug 2020 00:08:04

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:07:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2c933b79-d6d2-4f9d-bbb7-7da546186b50'	System	17 Aug 2020 00:08:04
User entered 'None (1)'	System	17 Aug 2020 00:08:04

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:01', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '2c933b79-d6d2-4f9d-bbb7-7da546186b50'	System	17 Aug 2020 00:08:04
User entered '16 Aug 2020 19:08'	System	17 Aug 2020 00:08:04

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'None (0)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:10', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'None (0)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'None (0)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'None (0)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'None (0)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:27', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'None (0)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:26:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered 'No (N)'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T10:27:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'b7615b79-815f-45ca-8afe-761764737044'	System	10 Aug 2020 15:27:02
User entered '10 Aug 2020 10:27'	System	10 Aug 2020 15:27:02

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:07'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:37'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:19', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b'	System	10 Aug 2020 23:01:16
User entered 'None (0)'	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:26', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b'	System	10 Aug 2020 23:01:16
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b'	System	10 Aug 2020 23:01:16
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b'	System	10 Aug 2020 23:01:16
User entered 'None (0)'	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b'	System	10 Aug 2020 23:01:16
User entered 'None (0)'	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b'	System	10 Aug 2020 23:01:16
User entered 'None (0)'	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:00:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b'	System	10 Aug 2020 23:01:16
User entered 'No (N)'	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-10T18:01:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'c6acc1bc-4c10-4dcd-9d8e-a3551ae6f97b'	System	10 Aug 2020 23:01:16
User entered '10 Aug 2020 18:01'	System	10 Aug 2020 23:01:16

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 13:32'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 2'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715'	System	11 Aug 2020 22:00:58
User entered 'None (0)'	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:11', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715'	System	11 Aug 2020 22:00:58
User entered 'None (0)'	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:17', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715'	System	11 Aug 2020 22:00:58
User entered 'None (0)'	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:22', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715'	System	11 Aug 2020 22:00:58
User entered 'None (0)'	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:33', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715'	System	11 Aug 2020 22:00:58
User entered 'None (0)'	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715'	System	11 Aug 2020 22:00:58
User entered 'None (0)'	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715'	System	11 Aug 2020 22:00:58
User entered 'No (N)'	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-11T17:00:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e239f591-1baa-4d0a-b961-f7323524f715'	System	11 Aug 2020 22:00:58
User entered '11 Aug 2020 17:00'	System	11 Aug 2020 22:00:58

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 3'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6'	System	12 Aug 2020 21:41:51
User entered 'None (0)'	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:40:56', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6'	System	12 Aug 2020 21:41:51
User entered 'No interference with activity (1)'	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:03', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6'	System	12 Aug 2020 21:41:51
User entered 'No interference with activity (1)'	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6'	System	12 Aug 2020 21:41:51
User entered 'None (0)'	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:10', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6'	System	12 Aug 2020 21:41:51
User entered 'None (0)'	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:13', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6'	System	12 Aug 2020 21:41:51
User entered 'None (0)'	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6'	System	12 Aug 2020 21:41:51
User entered 'No (N)'	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-12T16:41:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6b420ae-e23b-4662-9d6e-aea39e176fb6'	System	12 Aug 2020 21:41:51
User entered '12 Aug 2020 16:41'	System	12 Aug 2020 21:41:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 4'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed'	System	13 Aug 2020 20:15:14
User entered 'None (0)'	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed'	System	13 Aug 2020 20:15:14
User entered 'None (0)'	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed'	System	13 Aug 2020 20:15:14
User entered 'None (0)'	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed'	System	13 Aug 2020 20:15:14
User entered 'None (0)'	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed'	System	13 Aug 2020 20:15:14
User entered 'None (0)'	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:14:56', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed'	System	13 Aug 2020 20:15:14
User entered 'None (0)'	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:15:00', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed'	System	13 Aug 2020 20:15:14
User entered 'No (N)'	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-13T15:15:11', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '375f9da9-f53c-4234-bbeb-de6d229b9fed'	System	13 Aug 2020 20:15:14
User entered '13 Aug 2020 15:15'	System	13 Aug 2020 20:15:14

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 5'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:04', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f'	System	14 Aug 2020 20:53:51
User entered 'None (0)'	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f'	System	14 Aug 2020 20:53:51
User entered 'None (0)'	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f'	System	14 Aug 2020 20:53:51
User entered 'None (0)'	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:20', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f'	System	14 Aug 2020 20:53:51
User entered 'None (0)'	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:23', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f'	System	14 Aug 2020 20:53:51
User entered 'None (0)'	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:26', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f'	System	14 Aug 2020 20:53:51
User entered 'None (0)'	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f'	System	14 Aug 2020 20:53:51
User entered 'No (N)'	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-14T15:53:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3718da79-1192-4dcd-b5bb-41c7f5454e4f' User entered '14 Aug 2020 15:53'	System	14 Aug 2020 20:53:51
	System	14 Aug 2020 20:53:51

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 6'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91'	System	17 Aug 2020 00:04:54
User entered 'None (0)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:45', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91'	System	17 Aug 2020 00:04:54
User entered 'None (0)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91'	System	17 Aug 2020 00:04:54
User entered 'None (0)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91' User entered 'None (0)'	System	17 Aug 2020 00:04:54
	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:54', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91'	System	17 Aug 2020 00:04:54
User entered 'None (0)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:41:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91'	System	17 Aug 2020 00:04:54
User entered 'None (0)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:42:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91'	System	17 Aug 2020 00:04:54
User entered 'No (N)'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-15T18:42:09', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '283e417d-aef0-497e-9619-aa640ab90a91'	System	17 Aug 2020 00:04:54
User entered '15 Aug 2020 18:42'	System	17 Aug 2020 00:04:54

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 7'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:21', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:23', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered 'None (0)'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfdc862'	System	17 Aug 2020 00:08:47
User entered 'No (N)'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-08-16T19:08:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '51518870-e27c-452d-8ff6-418a4cfd862'	System	17 Aug 2020 00:08:47
User entered '16 Aug 2020 19:08'	System	17 Aug 2020 00:08:47

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 15:07:32

US3812098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	18 Aug 2020 18:27:45

US3812098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Angie Kean (b) (4) (b) (4)	18 Aug 2020 18:27:45

US3812098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4) (b) (4)	18 Aug 2020 18:27:45

US3812098

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Angie Kean (b) (4) (b) (4)	18 Aug 2020 18:27:45

US3812098

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 14:22:04

US3812098

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 14:22:04

US3812098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:17

US3812098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:17

US3812098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:17

US3812098

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:17

US3812098

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:23

US3812098

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 14:05:23

US3812098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:47

US3812098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:45:27
User entered '1 Sep 2020'	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:47

US3812098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:47

US3812098

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:47

US3812098

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Sep 2020 14:05:56

US3812098

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 14:05:56

US3812098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Sep 2020 14:06:11

US3812098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Heather Cherniawski (b) (4)	10 Sep 2020 14:06:11

US3812098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	10 Sep 2020 14:06:11

US3812098

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	10 Sep 2020 14:06:11

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '08:08'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 08:08'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.0' F	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '12'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '09:08'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 09:08'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '12'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '90'	Heather Cherniawski (b) (4)	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 16:08:20

US3812098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:03:36

US3812098

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 16:03:36

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Heather Cherniawski (b) (4)	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '08:37'	Heather Cherniawski (b) (4)	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 08:37'	System	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski (b) (4)	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 14:06:31

US3812098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:24

US3812098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:24

US3812098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '08:24'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:24

US3812098

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 08:24'	System	14 Sep 2020 16:04:24

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:20:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '08:27'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 08:27'	System	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Heather Cherniawski (b) (4)	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:04:45

US3812098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 03:40:57

US3812098

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 03:40:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:12:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6f29a702-5b31-4081-95a6-84a6f10ebd80'	System	10 Sep 2020 14:12:59
User entered 'Yes (Y)'	System	10 Sep 2020 14:12:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:12:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6f29a702-5b31-4081-95a6-84a6f10ebd80'	System	10 Sep 2020 14:12:59
User entered '97.7'	System	10 Sep 2020 14:12:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:12:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6f29a702-5b31-4081-95a6-84a6f10ebd80'	System	10 Sep 2020 14:12:59
User entered 'No (N)'	System	10 Sep 2020 14:12:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:12:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6f29a702-5b31-4081-95a6-84a6f10ebd80'	System	10 Sep 2020 14:12:59
User entered '10 Sep 2020 09:12'	System	10 Sep 2020 14:12:59

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 08:57'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:27'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:21', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f'	System	10 Sep 2020 22:02:55
User entered 'Yes (Y)'	System	10 Sep 2020 22:02:55

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:26', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f'	System	10 Sep 2020 22:02:55
User entered '99.8'	System	10 Sep 2020 22:02:55

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f'	System	10 Sep 2020 22:02:55
User entered 'Yes (Y)'	System	10 Sep 2020 22:02:55

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject was contacted' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 13:27:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f'	Karen Knapp (b) (4)	20 Sep 2020 17:30:57
User entered '1'	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f' User entered '0'	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:02:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '87fad030-1f04-41ae-93a7-7330f49b3d5f' User entered '10 Sep 2020 17:02'	System	10 Sep 2020 22:02:55
	System	10 Sep 2020 22:02:55

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:22'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 2'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:15', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac'	System	11 Sep 2020 20:13:57
User entered 'Yes (Y)'	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac'	System	11 Sep 2020 20:13:57
User entered '98.1'	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:30', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac'	System	11 Sep 2020 20:13:57
User entered 'Yes (Y)'	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject was contacted' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 13:27:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac' User entered '1'	Karen Knapp (b) (4)	20 Sep 2020 17:31:06
	System	11 Sep 2020 20:13:57
	System	11 Sep 2020 20:13:57
	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac' User entered '0'	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:13:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '40534057-e04d-47ae-ae93-d2ab1b2ca1ac'	System	11 Sep 2020 20:13:57
User entered '11 Sep 2020 15:13'	System	11 Sep 2020 20:13:57

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 3'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:08:27', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '445c806f-b982-421f-bed6-bc1195baee1a'	System	13 Sep 2020 15:09:09
User entered 'Yes (Y)'	System	13 Sep 2020 15:09:09

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:08:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '445c806f-b982-421f-bed6-bc1195baee1a' User entered '98.4'	System	13 Sep 2020 15:09:09
	System	13 Sep 2020 15:09:09

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:08:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '445c806f-b982-421f-bed6-bc1195baee1a'	System	13 Sep 2020 15:09:09
User entered 'No (N)'	System	13 Sep 2020 15:09:09

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:08:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '445c806f-b982-421f-bed6-bc1195baee1a' User entered '13 Sep 2020 10:08'	System	13 Sep 2020 15:09:09
	System	13 Sep 2020 15:09:09

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 4'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:41:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'efea882f-ac67-4d1e-bbbb-bff8b4c14d13'	System	13 Sep 2020 19:42:18
User entered 'Yes (Y)'	System	13 Sep 2020 19:42:18

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:41:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'efea882f-ac67-4d1e-bbbb-bff8b4c14d13'	System	13 Sep 2020 19:42:18
User entered '98.9'	System	13 Sep 2020 19:42:18

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'efea882f-ac67-4d1e-bbbb-bff8b4c14d13'	System	13 Sep 2020 19:42:18
User entered 'No (N)'	System	13 Sep 2020 19:42:18

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'efea882f-ac67-4d1e-bbbb-bff8b4c14d13'	System	13 Sep 2020 19:42:18
User entered '13 Sep 2020 14:42'	System	13 Sep 2020 19:42:18

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 5'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '1f875aa6-16b7-458b-9155-b96eb399496a'	System	14 Sep 2020 23:20:37
User entered 'Yes (Y)'	System	14 Sep 2020 23:20:37

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '1f875aa6-16b7-458b-9155-b96eb399496a' User entered '98.2'	System	14 Sep 2020 23:20:37

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:30', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '1f875aa6-16b7-458b-9155-b96eb399496a'	System	14 Sep 2020 23:20:37
User entered 'No (N)'	System	14 Sep 2020 23:20:37

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:35', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '1f875aa6-16b7-458b-9155-b96eb399496a'	System	14 Sep 2020 23:20:37
User entered '14 Sep 2020 18:20'	System	14 Sep 2020 23:20:37

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 6'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:19', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e7c2fd79-0658-4edc-9976-34dbba97aea3'	System	15 Sep 2020 23:38:45
User entered 'Yes (Y)'	System	15 Sep 2020 23:38:45

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e7c2fd79-0658-4edc-9976-34dbba97aea3' User entered '98.7'	System	15 Sep 2020 23:38:45

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:35', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e7c2fd79-0658-4edc-9976-34dbba97aea3'	System	15 Sep 2020 23:38:45
User entered 'No (N)'	System	15 Sep 2020 23:38:45

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e7c2fd79-0658-4edc-9976-34dbba97aea3'	System	15 Sep 2020 23:38:45
User entered '15 Sep 2020 18:38'	System	15 Sep 2020 23:38:45

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 7'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:49:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f21e033a-f3fe-442a-ab8a-6e710c816bca' User entered 'Yes (Y)'	System	16 Sep 2020 22:50:06
	System	16 Sep 2020 22:50:06

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:49:44', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f21e033a-f3fe-442a-ab8a-6e710c816bca' User entered '98.3'	System	16 Sep 2020 22:50:06

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:49:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f21e033a-f3fe-442a-ab8a-6e710c816bca'	System	16 Sep 2020 22:50:06
User entered 'No (N)'	System	16 Sep 2020 22:50:06

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:03', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'f21e033a-f3fe-442a-ab8a-6e710c816bca' User entered '16 Sep 2020 17:50'	System	16 Sep 2020 22:50:06
	System	16 Sep 2020 22:50:06

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9f8f3b80-4fe0-4230-a95e-b9cfc7746b'	System	10 Sep 2020 14:13:39
User entered 'None (1)'	System	10 Sep 2020 14:13:39

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9f8f3b80-4fe0-4230-a95e-b9cfc7746b'	System	10 Sep 2020 14:13:39
User entered 'No (N)'	System	10 Sep 2020 14:13:39

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:19', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9f8f3b80-4fe0-4230-a95e-b9cfdc7746b'	System	10 Sep 2020 14:13:39
User entered 'No (N)'	System	10 Sep 2020 14:13:39

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9f8f3b80-4fe0-4230-a95e-b9cfdc7746b'	System	10 Sep 2020 14:13:39
User entered 'None (1)'	System	10 Sep 2020 14:13:39

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:36', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9f8f3b80-4fe0-4230-a95e-b9cfdc7746b' User entered '10 Sep 2020 09:13'	System	10 Sep 2020 14:13:39
	System	10 Sep 2020 14:13:39

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 08:57'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:27'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:03:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6a1fc69-48e7-46c9-a8e9-4fd31682e884'	System	10 Sep 2020 22:04:10
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 22:04:10

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:03:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6a1fc69-48e7-46c9-a8e9-4fd31682e884'	System	10 Sep 2020 22:04:10
User entered 'No (N)'	System	10 Sep 2020 22:04:10

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:03:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6a1fc69-48e7-46c9-a8e9-4fd31682e884'	System	10 Sep 2020 22:04:10
User entered 'No (N)'	System	10 Sep 2020 22:04:10

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:03:56', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6a1fc69-48e7-46c9-a8e9-4fd31682e884'	System	10 Sep 2020 22:04:10
User entered 'None (1)'	System	10 Sep 2020 22:04:10

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6a1fc69-48e7-46c9-a8e9-4fd31682e884'	System	10 Sep 2020 22:04:10
User entered '10 Sep 2020 17:04'	System	10 Sep 2020 22:04:10

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:22'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 2'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:03', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd22625f8-a851-4318-837e-b55ce853a9ee'	System	11 Sep 2020 20:14:29
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 20:14:29

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd22625f8-a851-4318-837e-b55ce853a9ee'	System	11 Sep 2020 20:14:29
User entered 'No (N)'	System	11 Sep 2020 20:14:29

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd22625f8-a851-4318-837e-b55ce853a9ee'	System	11 Sep 2020 20:14:29
User entered 'No (N)'	System	11 Sep 2020 20:14:29

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd22625f8-a851-4318-837e-b55ce853a9ee'	System	11 Sep 2020 20:14:29
User entered 'None (1)'	System	11 Sep 2020 20:14:29

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd22625f8-a851-4318-837e-b55ce853a9ee'	System	11 Sep 2020 20:14:29
User entered '11 Sep 2020 15:14'	System	11 Sep 2020 20:14:29

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 3'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:08:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7bfa7f1d-5154-4eb9-969f-02246920354c'	System	13 Sep 2020 15:09:36
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 15:09:36

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:03', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7bfa7f1d-5154-4eb9-969f-02246920354c'	System	13 Sep 2020 15:09:36
User entered 'No (N)'	System	13 Sep 2020 15:09:36

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7bfa7f1d-5154-4eb9-969f-02246920354c'	System	13 Sep 2020 15:09:36
User entered 'No (N)'	System	13 Sep 2020 15:09:36

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:09', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7bfa7f1d-5154-4eb9-969f-02246920354c'	System	13 Sep 2020 15:09:36
User entered 'None (1)'	System	13 Sep 2020 15:09:36

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:18', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '7bfa7f1d-5154-4eb9-969f-02246920354c'	System	13 Sep 2020 15:09:36
User entered '13 Sep 2020 10:09'	System	13 Sep 2020 15:09:36

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 4'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:22', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e25f5e3c-4c43-407c-834b-5851ff3f34ab'	System	13 Sep 2020 19:42:49
User entered 'None (1)'	System	13 Sep 2020 19:42:49

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:27', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e25f5e3c-4c43-407c-834b-5851ff3f34ab'	System	13 Sep 2020 19:42:49
User entered 'No (N)'	System	13 Sep 2020 19:42:49

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e25f5e3c-4c43-407c-834b-5851ff3f34ab'	System	13 Sep 2020 19:42:49
User entered 'No (N)'	System	13 Sep 2020 19:42:49

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:35', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e25f5e3c-4c43-407c-834b-5851ff3f34ab'	System	13 Sep 2020 19:42:49
User entered 'None (1)'	System	13 Sep 2020 19:42:49

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'e25f5e3c-4c43-407c-834b-5851ff3f34ab' User entered '13 Sep 2020 14:42'	System	13 Sep 2020 19:42:49
	System	13 Sep 2020 19:42:49

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 5'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:41', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee46c763-a1d1-4d7c-b61d-33b0504a9b93'	System	14 Sep 2020 23:21:11
User entered 'None (1)'	System	14 Sep 2020 23:21:11

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:46', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee46c763-a1d1-4d7c-b61d-33b0504a9b93'	System	14 Sep 2020 23:21:11
User entered 'No (N)'	System	14 Sep 2020 23:21:11

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:20:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee46c763-a1d1-4d7c-b61d-33b0504a9b93'	System	14 Sep 2020 23:21:11
User entered 'No (N)'	System	14 Sep 2020 23:21:11

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee46c763-a1d1-4d7c-b61d-33b0504a9b93'	System	14 Sep 2020 23:21:11
User entered 'None (1)'	System	14 Sep 2020 23:21:11

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ee46c763-a1d1-4d7c-b61d-33b0504a9b93'	System	14 Sep 2020 23:21:11
User entered '14 Sep 2020 18:21'	System	14 Sep 2020 23:21:11

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 6'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '22740705-d95e-46f6-b314-26848e84ca92'	System	15 Sep 2020 23:39:34
User entered 'None (1)'	System	15 Sep 2020 23:39:34

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '22740705-d95e-46f6-b314-26848e84ca92'	System	15 Sep 2020 23:39:34
User entered 'No (N)'	System	15 Sep 2020 23:39:34

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:38:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '22740705-d95e-46f6-b314-26848e84ca92'	System	15 Sep 2020 23:39:34
User entered 'No (N)'	System	15 Sep 2020 23:39:34

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '22740705-d95e-46f6-b314-26848e84ca92'	System	15 Sep 2020 23:39:34
User entered 'None (1)'	System	15 Sep 2020 23:39:34

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '22740705-d95e-46f6-b314-26848e84ca92'	System	15 Sep 2020 23:39:34
User entered '15 Sep 2020 18:39'	System	15 Sep 2020 23:39:34

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 7'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:08', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '950d0f87-c8e6-4049-a6e7-676a3011920e'	System	16 Sep 2020 22:50:35
User entered 'None (1)'	System	16 Sep 2020 22:50:35

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:13', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '950d0f87-c8e6-4049-a6e7-676a3011920e'	System	16 Sep 2020 22:50:35
User entered 'No (N)'	System	16 Sep 2020 22:50:35

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:17', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '950d0f87-c8e6-4049-a6e7-676a3011920e'	System	16 Sep 2020 22:50:35
User entered 'No (N)'	System	16 Sep 2020 22:50:35

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:21', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '950d0f87-c8e6-4049-a6e7-676a3011920e'	System	16 Sep 2020 22:50:35
User entered 'None (1)'	System	16 Sep 2020 22:50:35

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '950d0f87-c8e6-4049-a6e7-676a3011920e' User entered '16 Sep 2020 17:50'	System	16 Sep 2020 22:50:35
	System	16 Sep 2020 22:50:35

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:44', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec'	System	10 Sep 2020 14:14:08
User entered 'None (0)'	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:47', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec'	System	10 Sep 2020 14:14:08
User entered 'None (0)'	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:50', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec'	System	10 Sep 2020 14:14:08
User entered 'None (0)'	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec'	System	10 Sep 2020 14:14:08
User entered 'None (0)'	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:56', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec'	System	10 Sep 2020 14:14:08
User entered 'None (0)'	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:13:58', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec'	System	10 Sep 2020 14:14:08
User entered 'None (0)'	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:14:01', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec'	System	10 Sep 2020 14:14:08
User entered 'No (N)'	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T09:14:06', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'ff918b9a-03a3-4bd5-b6d6-bbac0a2875ec'	System	10 Sep 2020 14:14:08
User entered '10 Sep 2020 09:14'	System	10 Sep 2020 14:14:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 08:57'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:27'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009'	System	10 Sep 2020 22:05:19
User entered 'None (0)'	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:19', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009'	System	10 Sep 2020 22:05:19
User entered 'No interference with activity (1)'	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:28', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009'	System	10 Sep 2020 22:05:19
User entered 'None (0)'	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009'	System	10 Sep 2020 22:05:19
User entered 'None (0)'	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:38', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009'	System	10 Sep 2020 22:05:19
User entered 'None (0)'	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009'	System	10 Sep 2020 22:05:19
User entered 'None (0)'	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:04:50', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009'	System	10 Sep 2020 22:05:19
User entered 'No (N)'	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-10T17:05:16', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '29ae7cf9-cff6-4bd4-bd68-c2dcfd7b6009'	System	10 Sep 2020 22:05:19
User entered '10 Sep 2020 17:05'	System	10 Sep 2020 22:05:19

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:22'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 2'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered 'None (0)'	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered 'Some interference with activity (2)'	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered 'None (0)'	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:14:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered 'None (0)'	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:15:01', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered 'None (0)'	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:15:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered 'No interference with activity (1)'	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:15:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered 'No (N)'	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-11T15:15:38', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '745b3658-8686-4a40-8fab-2787703ea398'	System	11 Sep 2020 20:15:42
User entered '11 Sep 2020 15:15'	System	11 Sep 2020 20:15:42

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 3'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:24', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836'	System	13 Sep 2020 15:09:50
User entered 'None (0)'	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:26', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836'	System	13 Sep 2020 15:09:50
User entered 'None (0)'	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836'	System	13 Sep 2020 15:09:50
User entered 'None (0)'	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:31', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836'	System	13 Sep 2020 15:09:50
User entered 'None (0)'	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836'	System	13 Sep 2020 15:09:50
User entered 'None (0)'	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836'	System	13 Sep 2020 15:09:50
User entered 'None (0)'	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836'	System	13 Sep 2020 15:09:50
User entered 'No (N)'	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T10:09:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'd77240ab-945e-4575-8eda-d0afb16d6836'	System	13 Sep 2020 15:09:50
User entered '13 Sep 2020 10:09'	System	13 Sep 2020 15:09:50

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 4'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722'	System	13 Sep 2020 19:43:27
User entered 'None (0)'	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:56', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722'	System	13 Sep 2020 19:43:27
User entered 'None (0)'	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:42:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722'	System	13 Sep 2020 19:43:27
User entered 'None (0)'	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:43:02', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722'	System	13 Sep 2020 19:43:27
User entered 'None (0)'	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:43:04', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722'	System	13 Sep 2020 19:43:27
User entered 'None (0)'	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:43:07', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722'	System	13 Sep 2020 19:43:27
User entered 'None (0)'	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:43:11', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722'	System	13 Sep 2020 19:43:27
User entered 'No (N)'	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-13T14:43:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '9835ef65-5983-41c9-aa27-cd0f05136722'	System	13 Sep 2020 19:43:27
User entered '13 Sep 2020 14:43'	System	13 Sep 2020 19:43:27

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 5'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:14', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b'	System	14 Sep 2020 23:21:54
User entered 'None (0)'	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:17', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b'	System	14 Sep 2020 23:21:54
User entered 'None (0)'	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:20', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b'	System	14 Sep 2020 23:21:54
User entered 'None (0)'	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:25', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b'	System	14 Sep 2020 23:21:54
User entered 'None (0)'	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b'	System	14 Sep 2020 23:21:54
User entered 'None (0)'	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:32', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b'	System	14 Sep 2020 23:21:54
User entered 'None (0)'	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:38', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b'	System	14 Sep 2020 23:21:54
User entered 'No (N)'	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-14T18:21:51', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '435f6f56-30bf-4649-b0c4-f2d86723b66b'	System	14 Sep 2020 23:21:54
User entered '14 Sep 2020 18:21'	System	14 Sep 2020 23:21:54

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 6'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:36', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098'	System	15 Sep 2020 23:40:17
User entered 'None (0)'	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098'	System	15 Sep 2020 23:40:17
User entered 'None (0)'	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:44', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098'	System	15 Sep 2020 23:40:17
User entered 'None (0)'	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098'	System	15 Sep 2020 23:40:17
User entered 'None (0)'	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:52', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098'	System	15 Sep 2020 23:40:17
User entered 'None (0)'	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:39:54', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098'	System	15 Sep 2020 23:40:17
User entered 'None (0)'	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:40:01', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098'	System	15 Sep 2020 23:40:17
User entered 'No (N)'	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-15T18:40:12', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'fbce7665-3fb9-4dd1-bbbb-37e288cbc098'	System	15 Sep 2020 23:40:17
User entered '15 Sep 2020 18:40'	System	15 Sep 2020 23:40:17

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:06:31
User entered 'Day 7'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5'	System	16 Sep 2020 22:51:08
User entered 'None (0)'	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:40', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5'	System	16 Sep 2020 22:51:08
User entered 'None (0)'	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:45', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5'	System	16 Sep 2020 22:51:08
User entered 'None (0)'	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:50', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5'	System	16 Sep 2020 22:51:08
User entered 'None (0)'	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:53', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5'	System	16 Sep 2020 22:51:08
User entered 'None (0)'	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5'	System	16 Sep 2020 22:51:08
User entered 'None (0)'	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:50:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5'	System	16 Sep 2020 22:51:08
User entered 'No (N)'	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-09-16T17:51:05', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '0b66e864-de8f-484a-b615-ac05466995e5'	System	16 Sep 2020 22:51:08
User entered '16 Sep 2020 17:51'	System	16 Sep 2020 22:51:08

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:06:31

US3812098

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:06:31

US3812098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	17 Sep 2020 18:05:00

US3812098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Karen Knapp (b) (4) (b) (4)	17 Sep 2020 18:05:00

US3812098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	17 Sep 2020 18:05:00

US3812098

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	17 Sep 2020 18:05:00

US3812098

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	17 Sep 2020 18:05:06

US3812098

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:05:06

US3812098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	24 Sep 2020 19:03:18

US3812098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Karen Knapp (b) (4) (b) (4)	24 Sep 2020 19:03:18

US3812098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	24 Sep 2020 19:03:18

US3812098

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	24 Sep 2020 19:03:18

US3812098

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	24 Sep 2020 19:03:23

US3812098

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 19:03:23

US3812098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	01 Oct 2020 18:42:44

US3812098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '01 Oct 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:46:13
User entered '1 Oct 2020'	Karen Knapp (b) (4)	01 Oct 2020 18:42:44

US3812098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	01 Oct 2020 18:42:44

US3812098

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	01 Oct 2020 18:42:44

US3812098

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	01 Oct 2020 18:42:48

US3812098

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 18:42:48

US3812098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:43:58

US3812098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '09 Oct 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:46:30
User entered '9 Oct 2020'	Breanna Galibert (b) (4)	09 Oct 2020 17:43:58

US3812098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:43:58

US3812098

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	09 Oct 2020 17:43:58

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Oct 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:46:42
User entered '9 Oct 2020'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '09:50'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '09 Oct 2020 09:50'	System	10 Nov 2020 17:46:42
User entered '9 Oct 2020 09:50'	System	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '17'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 17:44:20

US3812098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:40

US3812098

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '09 Oct 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:47:04
User entered '9 Oct 2020'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:40

US3812098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:51

US3812098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '09 Oct 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:47:12
User entered '9 Oct 2020'	Breanna Galibert (b) (4)	09 Oct 2020 17:44:51

US3812098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:20'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:44:51

US3812098

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '09 Oct 2020 10:20'	System	10 Nov 2020 17:47:12
User entered '9 Oct 2020 10:20'	System	09 Oct 2020 17:44:51

US3812098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	18 Oct 2020 15:37:06

US3812098

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 15:37:06

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 64'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-14T08:43:49', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '04dc6c0a-e8e3-4a51-9b14-03f4f4329243'	System	14 Oct 2020 13:44:43
User entered 'Yes (Y)'	System	14 Oct 2020 13:44:43

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-14T08:43:59', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '04dc6c0a-e8e3-4a51-9b14-03f4f4329243'	System	14 Oct 2020 13:44:43
User entered 'No (N)'	System	14 Oct 2020 13:44:43

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-14T08:44:13', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '04dc6c0a-e8e3-4a51-9b14-03f4f4329243'	System	14 Oct 2020 13:44:43
User entered 'No (N)'	System	14 Oct 2020 13:44:43

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-14T08:44:22', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '04dc6c0a-e8e3-4a51-9b14-03f4f4329243'	System	14 Oct 2020 13:44:43
User entered 'No (N)'	System	14 Oct 2020 13:44:43

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-14T08:44:39', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '04dc6c0a-e8e3-4a51-9b14-03f4f4329243' User entered '14 Oct 2020 08:44:39'	System	14 Oct 2020 13:44:43
	System	14 Oct 2020 13:44:43

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 71'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-20T12:13:15', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a18ba5e2-ec39-48e3-bebf-f4ebdb115c8a'	System	20 Oct 2020 17:13:35
User entered 'No (N)'	System	20 Oct 2020 17:13:35

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-20T12:13:20', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a18ba5e2-ec39-48e3-bebf-f4ebdb115c8a'	System	20 Oct 2020 17:13:35
User entered 'No (N)'	System	20 Oct 2020 17:13:35

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-20T12:13:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a18ba5e2-ec39-48e3-bebf-f4ebdb115c8a' User entered '20 Oct 2020 12:13:29'	System	20 Oct 2020 17:13:35
	System	20 Oct 2020 17:13:35

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 78'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-27T07:26:34', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6865674-c7e9-4d6f-893c-56b1de9847ff'	System	27 Oct 2020 12:27:00
User entered 'No (N)'	System	27 Oct 2020 12:27:00

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-27T07:26:42', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6865674-c7e9-4d6f-893c-56b1de9847ff'	System	27 Oct 2020 12:27:00
User entered 'No (N)'	System	27 Oct 2020 12:27:00

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-10-27T07:26:57', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: 'a6865674-c7e9-4d6f-893c-56b1de9847ff' User entered '27 Oct 2020 07:26:57'	System	27 Oct 2020 12:27:00
	System	27 Oct 2020 12:27:00

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 92'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-11T08:14:29', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6d63c9eb-1b4e-4282-baae-89aab71e07e1'	System	11 Nov 2020 14:14:48
User entered 'No (N)'	System	11 Nov 2020 14:14:48

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-11T08:14:37', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6d63c9eb-1b4e-4282-baae-89aab71e07e1'	System	11 Nov 2020 14:14:48
User entered 'No (N)'	System	11 Nov 2020 14:14:48

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-11T08:14:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '6d63c9eb-1b4e-4282-baae-89aab71e07e1' User entered '11 Nov 2020 08:14:43'	System	11 Nov 2020 14:14:48
	System	11 Nov 2020 14:14:48

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered 'Day 99'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-17T12:54:43', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3c745204-8cbb-4aae-b95d-379539afd65e'	System	17 Nov 2020 18:54:59
User entered 'No (N)'	System	17 Nov 2020 18:54:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Have you been exposed to someone with 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 (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-17T12:54:48', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3c745204-8cbb-4aae-b95d-379539afd65e'	System	17 Nov 2020 18:54:59
User entered 'No (N)'	System	17 Nov 2020 18:54:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFBC6CDF-308E-456A-BAC1-864A6C91A2FA)', Time: '2020-11-17T12:54:55', User OID: 'PatientReportedOutcome (US3812098)', ODM File OID: '3c745204-8cbb-4aae-b95d-379539afd65e' User entered '17 Nov 2020 12:54:55'	System	17 Nov 2020 18:54:59
	System	17 Nov 2020 18:54:59

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 15:07:32

US3812098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 15:07:32
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 15:07:32

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Oct 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 Oct 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Oct 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Oct 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Oct 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Oct 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 16:59:17

US3812098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:17
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 16:59:17

US3812098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	05 Nov 2020 15:48:40

US3812098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '05 Nov 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	10 Nov 2020 17:47:38
User entered '5 Nov 2020'	Karen Knapp (b) (4)	05 Nov 2020 15:48:40

US3812098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	05 Nov 2020 15:48:40

US3812098

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	05 Nov 2020 15:48:40

US3812098

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	05 Nov 2020 15:48:44

US3812098

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 15:48:44

US3812098

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:20:44

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	30 Oct 2020 21:24:13

US3812098

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:20:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:46
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	15 Sep 2020 03:41:15
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 14:21:51

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:24:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:41
User entered 'USA-US111-2020-mRNA-1273-P301000005'	System	15 Oct 2020 12:46:37
User entered 'New'	(b) (4), (b) (6)	15 Oct 2020 12:46:37

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:40
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:26:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:26:36
Data point term sent to Coder	System	14 Oct 2020 18:26:12
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 18:25:43
User entered 'Prostate Cancer' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:25:43
User coded data point as SOC: Investigations, HLGT: Cytogenetic investigations, HLT: Cell marker analyses, PT: Prostatic specific antigen increased, LLT: PSA increased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 03:44:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 03:44:33
Data point term sent to Coder	System	15 Sep 2020 03:43:40
User entered 'ELEVATED PSA'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:44
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:46
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:48
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:49:37
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	15 Sep 2020 03:42:54
User entered '28 Aug 2020'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:09:12
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:28:25
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time.' answered with 'End date not available at this time. Will update once resolved.' (Site from Safety).	Lyly Dang (b) (4)	13 Nov 2020 19:56:31
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:24:51
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition), then the SAE is considered resolved with sequelae and an end date should be associated at that time.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:25:00
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)	30 Oct 2020 12:10:46
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 'SUBJECT STILL HAS ACTIVE CANCER, AE HAS NO END DATE.' (Site from Safety).	Heather Cherniawski (b) (4)	28 Oct 2020 16:15:10
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)	23 Oct 2020 17:40:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:24:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:53
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:25:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:37:56
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:25:43
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

US3812098

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:17:17
User closed query 'PV Query: The event seriousness criteria was reclassified from life-threatening to medically significant. However, the EDC was not updated. Please clarify and if necessary update the EDC.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 20:26:36
Query 'PV Query: The event seriousness criteria was reclassified from life-threatening to medically significant. However, the EDC was not updated. Please clarify and if necessary update the EDC.' answered with 'updated' (Site from Safety).	Lyly Dang (b) (4)	05 Nov 2020 22:20:51
DataPoint Un-verified.	Lyly Dang (b) (4)	05 Nov 2020 22:20:40
User entered '0' reason for change: New Information	Lyly Dang (b) (4)	05 Nov 2020 22:20:40
User opened query 'PV Query: The event seriousness criteria was reclassified from life-threatening to medically significant. However, the EDC was not updated. Please clarify and if necessary update the EDC.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:22:20
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:38:01
User entered '1' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:25:43
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 03:17:22
User closed query 'Per source other medically important event is checked and not life threatening per source. Please confirm with source and update accordingly. ?	(b) (4), (b) (6)	16 Nov 2020 03:17:21

Cancel

' (Site from CRA).

Query 'Per source other medically important event is checked and not life threatening per source. Please confirm with source and update accordingly. ?	Lyly Dang (b) (4)	05 Nov 2020 22:20:56

Cancel

' answered with 'updated' (Site from CRA).

DataPoint Un-verified.	Lyly Dang (b) (4)	05 Nov 2020 22:20:40

User entered '1' reason for change: Data Entry Error	Lyly Dang (b) (4)	05 Nov 2020 22:20:40

DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56

User opened query 'Per source other medically important event is checked and not life threatening per source. Please confirm with source and update accordingly. ?	(b) (4), (b) (6)	05 Nov 2020 20:29:12

Cancel

' (Site from CRA).

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Query 'Per source other medically important event is checked. Please update life threatening per source. Please confirm with source and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 20:28:30
User opened query 'Per source other medically important event is checked. Please update life threatening per source. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 20:28:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:50
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:52
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:25:48
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:58:29
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'conmed ceftriaxone indication updated to match AE term' (Site from DM).	Anya Penly (b) (4)	12 Nov 2020 21:13:29
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 03:59:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '1' reason for change: Data Entry Error	Breanna Galibert (b) (4)	09 Oct 2020 17:47:17
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: RQ: Response noted, however, the procedure recorded in the Con Proc eCRF for this AE is diagnostic. Review if there is a therapeutic procedure done and record as appropriate. Otherwise, update the response.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:50:36
Query 'Per DM CLR: RQ: Response noted, however, the procedure recorded in the Con Proc eCRF for this AE is diagnostic. Review if there is a therapeutic procedure done and record as appropriate. Otherwise, update the response.' answered with 'no therapeutic procedure done at this time. ' (Site from DM).	Anya Penly (b) (4)	12 Nov 2020 21:25:41
User opened query 'Per DM CLR: RQ: Response noted, however, the procedure recorded in the Con Proc eCRF for this AE is diagnostic. Review if there is a therapeutic procedure done and record as appropriate. Otherwise, update the response.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 03:57:39
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:43:49
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'BIOPSY OF PROSTATE on 02 OCT 2020 is recorded in con procedures' (Site from DM).	Anya Penly (b) (4)	21 Oct 2020 14:41:35
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:01:07
User entered '1'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:25:15
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)	30 Oct 2020 12:10:50
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 'Subject not resolved. Expecting resolution before the end of the trial per Sub I Clement NPC' (Site from Safety).	Heather Cherniawski (b) (4)	28 Oct 2020 16:20:01
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)	23 Oct 2020 17:40:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:50
User closed query 'PV Query: Will the subject receive any treatment for prostate cancer (i.e. radiation, surgery, etc)?' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:28:33
Query 'PV Query: Will the subject receive any treatment for prostate cancer (i.e. radiation, surgery, etc)?' answered with 'Subject is scheduled for a prostatectomy on 13 Jan 2021' (Site from Safety).	Lyly Dang (b) (4)	13 Nov 2020 19:55:52
User entered '14 OCT 2020 AT 10:30 AM-SUBJECT CALLED TODAY AND REPORTED ELEVATED PSA IS NOW A DIAGNOSIS OF PROSTATE CANCER. PSA LEVEL COLLECTED ON AUG 03, 2020 WAS 6.0 NG/ML. Subject is scheduled for a prostatectomy on 13 Jan 2021. Subject denies any other changes in treatment or medications at this time.' reason for change: New Information	Lyly Dang (b) (4)	13 Nov 2020 19:54:07
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 19:06:26
User closed query 'PV Query: Please provide the subject's PSA levels prior to study enrollment and on 28 AUG 2020 (screening for prostate cancer).' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 20:26:49
Query 'PV Query: Please provide the subject's PSA levels prior to study enrollment and on 28 AUG 2020 (screening for prostate cancer).' answered with 'updated' (Site from Safety).	Lyly Dang (b) (4)	05 Nov 2020 22:21:03
DataPoint Un-verified.	Lyly Dang (b) (4)	05 Nov 2020 22:20:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Narrative](#)

Audit	User	Time (GMT)
User entered '14 OCT 2020 AT 10:30 AM-SUBJECT CALLED TODAY AND REPORTED ELEVATED PSA IS NOW A DIAGNOSIS OF PROSTATE CANCER. PSA level collected on Aug 03, 2020 was 6.0 ng/mL. WILL RETRIEVE MR FOR THIS DIAGNOSIS. SUBJECT REPORTS HE HAS NOT GOTTEN A PLAN YET FOR DX AND IS GOING TO MAKE A FOLLOW UP APPOINTMENT SOON.' reason for change: New Information	Lyly Dang (b) (4)	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:26:00
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:10:51
User opened query 'PV Query: Will the subject receive any treatment for prostate cancer (i.e. radiation, surgery, etc)? ' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:21:41
User opened query 'PV Query: Please provide the subject's PSA levels prior to study enrollment and on 28 AUG 2020 (screening for prostate cancer). ' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:21:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Subject has not yet been seen for treatment plan. Will update when given and completing one per SUB I CLEMENT NPC' (Site from Safety).	Heather Cherniawski (b) (4)	28 Oct 2020 16:21:04
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:40:33
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Oct 2020 18:27:41
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Oct 2020 18:27:41
User entered '14 OCT 2020 at 10:30 AM- Subject called today and reported elevated PSA is now a diagnosis of prostate cancer. Will retrieve MR for this diagnosis. Subject reports he has not gotten a plan yet for dx and is going to make a follow up appointment soon. Please note that subject just found out about prostate cancer dx yesterday.' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:27:41
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Oct 2020 18:25:43
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:25:43
User entered '0'	System	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 03:42:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:59:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:59:53
Data point term sent to Coder	System	01 Oct 2020 19:59:07
User entered 'BILATERAL HIP PAIN'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '24 Sep 2020'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '1'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:58:11
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 19:58:11

US3812098

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:20:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 19:58:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
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)	01 Oct 2020 20:01:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:01:00
Data point term sent to Coder	System	01 Oct 2020 20:00:09
User entered 'NECK PAIN'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '22 Sep 2020' reason for change: Data Entry Error	Anya Penly (b) (4)	21 Oct 2020 14:35:22
User entered '24 Sep 2020'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:59:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '1'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 19:59:16
	(b) (4)	

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:20:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 19:59:16

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:40:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:40:02
Data point term sent to Coder	System	21 Oct 2020 14:35:09
User entered 'worsening left cataract'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Yes (Y)'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '15 Oct 2020'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Yes (Y)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Related (NOT RELATED)'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Not Applicable (NOT APPLICABLE)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered '1'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:31:56
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:34:43

US3812098

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:20:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:34:43

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:20:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:18:07
User closed query 'Per CDM Re-query: 'Was any medication taken today for pain and fever?' is recorded Yes from 10-sep-2020 to 12-sep-2020. Site response on Temperature day form, Diary Dose 2 folder (Dose Temp Log Line 2 and 3) indicates 'subject was contacted'. However, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update. Else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:10:02
Query 'Per CDM Re-query: 'Was any medication taken today for pain and fever?' is recorded Yes from 10-sep-2020 to 12-sep-2020. Site response on Temperature day form, Diary Dose 2 folder (Dose Temp Log Line 2 and 3) indicates 'subject was contacted'. However, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update. Else clarify.' answered with 'concomitant procedure added to EDC' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 18:31:26
User opened query 'Per CDM Re-query: 'Was any medication taken today for pain and fever?' is recorded Yes from 10-sep-2020 to 12-sep-2020. Site response on Temperature day form, Diary Dose 2 folder (Dose Temp Log Line 2 and 3) indicates 'subject was contacted'. However, corresponding concomitant medication has not been reported under Prior/Concomitant Medication and Vaccination section of the eCRF. Please review and update. Else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:26:05
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 18:58:51

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:02:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:02:15
Data point term sent to Coder	System	11 Aug 2020 19:00:40
User entered 'MULTIVITAMIN'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'GENERAL HEALTH'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '1'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'tablet (TABLET)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:48:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 19:00:34
User entered 'UN UNK 2010'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '0'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 19:00:34

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:04:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:04:30
Data point term sent to Coder Coding entries removed.	System Angie Kean (b) (4) (b) (4)	24 Nov 2020 16:03:38 24 Nov 2020 16:03:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:27:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:27:37
Data point term sent to Coder Coding entries removed.	System Any Penly (b) (4) (b) (4)	12 Nov 2020 21:11:30 12 Nov 2020 21:11:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:57:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:57:35
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	14 Oct 2020 18:29:15 14 Oct 2020 18:28:54

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:08:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:08:31
Data point term sent to Coder	System	09 Oct 2020 17:46:54
User entered 'ceftriaxone'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:00:49
DataPoint Un-verified.	Anya Penly (b) (4)	12 Nov 2020 21:11:13
User entered 'prostate cancer' reason for change:	(b) (4)	
Data Entry Error	Anya Penly (b) (4)	12 Nov 2020 21:11:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'PROSTATE BIOPSY for AE #1'	(b) (4), (b) (6)	14 Oct 2020 18:28:54
reason for change: Data Entry Error		
User entered 'prostate biopsy'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, 1 G, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UPDATED' (Site from DM). DataPoint Un-verified.	Angie Kean (b) (4) (b) (4)	24 Nov 2020 16:00:29
	Angie Kean (b) (4) (b) (4)	24 Nov 2020 16:00:05
User entered '2.4' reason for change: New Information	Angie Kean (b) (4) (b) (4)	24 Nov 2020 16:00:05
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, 1 G, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '1'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	24 Nov 2020 16:03:25
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	24 Nov 2020 16:00:05
DataPoint Un-verified.	Angie Kean (b) (4)	24 Nov 2020 16:00:05
User entered 'mg (mg)' reason for change: New Information	(b) (4)	
DataPoint Verified.	Angie Kean (b) (4)	24 Nov 2020 16:00:05
	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Other (OTHER)'	(b) (4)	
	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	Angie Kean (b) (4)	24 Nov 2020 16:03:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	24 Nov 2020 16:03:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'injection'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'once (ONCE)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Angie Kean (b) (4)	24 Nov 2020 16:03:25
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Angie Kean (b) (4)	24 Nov 2020 16:03:25
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Breanna Galibert (b) (4)	09 Oct 2020 17:46:08
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '02 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '02 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:46:08

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
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)	21 Oct 2020 14:32:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:32:40
Data point term sent to Coder	System	21 Oct 2020 14:30:59
User entered 'tylenol'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'pain at injection site'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '500'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'mg (mg)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'once daily (QD)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Oral (ORAL)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '10 Sep 2020'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '11 Sep 2020'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Yes (Y)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 14:30:42

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
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)	21 Oct 2020 14:34:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:34:19
Data point term sent to Coder	System	21 Oct 2020 14:33:04
User entered 'tylenol'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'bilateral hip pain and neck pain'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '500'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'mg (mg)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'once daily (QD)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Oral (ORAL)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '24 Sep 2020'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '0'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '24 Sep 2020'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 14:32:05

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 15:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 15:19:32
Data point term sent to Coder	System	21 Oct 2020 14:33:04
User entered 'aspirin'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'bilateral hip pain and neck pain'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '325'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'mg (mg)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'once daily (QD)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'Oral (ORAL)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered empty.	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '24 Sep 2020'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '0'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered '24 Sep 2020'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:02
User entered 'No (N)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 14:32:55

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:43:05
User closed query 'please correct spelling to prednisone' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:43:01
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: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:36:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:36:51
Data point term sent to Coder	System	20 Nov 2020 17:49:19
Query 'please correct spelling to prednisone' answered with 'UPDATED' (Site from CRA).	Angie Kean (b) (4) (b) (4)	20 Nov 2020 17:49:14
Coding entries removed.	Angie Kean (b) (4) (b) (4)	20 Nov 2020 17:49:08
User entered 'PREDNISONE' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	20 Nov 2020 17:49:08
Query 'prednisone is exclusionary for dose >20mg (Excl#12). Please file ePIP and PD.' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:12:37
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: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:53:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:53:54
User opened query 'prednisone is exclusionary for dose >20mg (Excl#12). Please file ePIP and PD.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:19:29
User opened query 'please correct spelling to prednisone' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 18:01:26
Data point term sent to Coder	System	16 Nov 2020 15:41:23

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US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'predinsone'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:01:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:01:58
User entered 'bilateral hip pain'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:00
User entered '50'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:05
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:07
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:09
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:13
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:15
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:17
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:19
User entered '04 Nov 2020'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:27
User entered '0'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:23
User entered 'No (N)'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:25
User entered '13 Nov 2020'	Breanna Galibert (b) (4)	16 Nov 2020 15:40:39
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:02:29
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 15:40:39

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 15:43:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 15:43:43
Data point term sent to Coder	System	16 Nov 2020 15:42:24
User entered 'pneumovax'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:18
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:20
User entered 'immunization'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:54
User entered '0.5'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:55
User entered 'mL (mL)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:26:57
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:01
User entered 'once (ONCE)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:03
User entered 'Intramuscular (INTRAMUSCULAR)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:05
User entered empty.	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:07
User entered '04 Nov 2020'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:08
User entered '0'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:11
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:12
User entered '04 Nov 2020'	Breanna Galibert (b) (4)	16 Nov 2020 15:41:37
	(b) (4)	

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:27:15
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 15:41:37

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:20:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:21:12
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 18:29:36
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 14:21:46

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:20:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered '02 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:30:29

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:20:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered 'Biopsy of Prostate'	(b) (4), (b) (6)	14 Oct 2020 18:30:29

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	14 Oct 2020 18:30:29

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:20:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:30:29

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:20:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered '15 Oct 2020'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:39:23

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:20:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered 'left cataract removal'	Anya Penly (b) (4) (b) (4)	21 Oct 2020 14:39:23

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered 'Adverse Event (AE)'	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:39:23

US3812098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:20:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:23:53
User entered empty.	Any Penly (b) (4) (b) (4)	21 Oct 2020 14:39:23

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'USA-US111-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'USA-US111-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:20:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
User entered '15/Oct/2020 12:47'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:20:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'USA-US111-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:20:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
User entered '22/Oct/2020 20:21'	System	23 Oct 2020 00:21:26

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:20:44

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)	06 Nov 2020 20:27:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 00:21:26

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'USA-US111-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:20:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '06/Nov/2020 20:27'	System	06 Nov 2020 20:27:39

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:20:44

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)	16 Nov 2020 14:29:39
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 20:27:39

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'USA-US111-2020-MRNA-1273-P301000005'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:54:31
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'No (N)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'Yes (Y)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Yes (Y)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:55:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 20:27:20
Un-reviewed for Safety.	System	05 Nov 2020 22:20:40
DataPoint Un-verified.	System	05 Nov 2020 22:20:40
User entered 'Yes (Y)'	System	05 Nov 2020 22:20:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'No (N)'	System	19 Oct 2020 16:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 16:58:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'No (N)'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Larkin'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'Wadsworth'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '711 Old Ballas Rd Suite 105'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered 'St Louis'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered empty.	System	19 Oct 2020 16:58:06
User entered 'MO'	(b) (4), (b) (6)	19 Oct 2020 16:57:34

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:46:58
User entered '63141'	System	15 Oct 2020 12:46:37

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:36:39
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 00:21:14
User entered 'US'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 11:20:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Nov 2020 14:29:53
User entered '3'	System	06 Nov 2020 20:27:39
User entered '2'	System	23 Oct 2020 00:21:26
User entered '1'	System	15 Oct 2020 12:47:06

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:20:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:00:21
User entered '16/Nov/2020 09:29'	System	16 Nov 2020 14:29:53

US3812098

Folder: SAE USA-US111-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:20:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:00:20
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 14:29:53