

US3462116 (Prod: Crisor, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:31:07

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US3462116

Form: Participant Creation

Generated On: 26 Nov 2020 09:31:07

[Participant ID](#)

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

US3462116

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	43
Age Units	YEARS
Age (Derived)	43
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:31:07

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:31:07

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

Condition	OCCASIONAL HEADACHES
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: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

Condition	HODGKINS LYMPHOMA
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

Condition	RIGHT ANKLE ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

Condition	RUPTURED L5
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

Condition	RUPTURED L6
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN NOV 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN NOV 2005
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2005
Start Year (derived)	2005
Stop Month and Year (derived)	NOV 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

Condition	RIGHT ANKLE JOINT FUSION
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

Condition	LUMBAR DISCECTOMY
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

Condition	LUMBAR DISECTOMY
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:58 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:58
Height (<i>xxx.x</i>)	173 cm
Weight (<i>xxx.x</i>)	108 kg
BMI (<i>xxx.x</i>)	36.08540 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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: Childbearing Potential

Generated On: 26 Nov 2020 09:31:07

Date of assessment (*dd MMM yyyy*) 11 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☒
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN NOV 2005

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:07

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 103130

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:07

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

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)	11 AUG 2020
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:58
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

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)	11 AUG 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 12:53
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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)	11 AUG 2020
What was the treatment time? (00:00-23:59)	12:22 (24 HR)
Treatment Date and Time (derived)	11 AUG 2020 12:22
Which arm was used to give treatment?	Left Arm ☐
	Right Arm ☒
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	11 AUG 2020
Collection time (<i>00:00-23:59</i>)	11:50 (24 HR)
Collection date and time (derived)	11 AUG 2020 11:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:07

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:52	11 AUG 2020 11:52
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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

93.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 12:55

PC Open Date & Time

11 AUG 2020 12:42

PC Close Date & Time

11 AUG 2020 15:12

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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 97.4 °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 16:10
PC Open Date & Time	11 AUG 2020 16:07
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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 12:41

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(3)

Generated On: 26 Nov 2020 09:31:07

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

98.0 °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

13 AUG 2020 12:08

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 14:59

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

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

98.0 °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

15 AUG 2020 12:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

16 AUG 2020 14:51

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:18

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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

11 AUG 2020 12:56

PC Open Date & Time

11 AUG 2020 12:42

PC Close Date & Time

11 AUG 2020 15:12

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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

4

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 16:12

PC Open Date & Time

11 AUG 2020 16:07

PC Close Date & Time

12 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:41

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:08

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

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

14 AUG 2020 15:00

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

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

15 AUG 2020 12:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

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

16 AUG 2020 14:51

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

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

17 AUG 2020 12:18

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 12:57
PC Open Date & Time	11 AUG 2020 12:42
PC Close Date & Time	11 AUG 2020 15:12

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 16:12
PC Open Date & Time	11 AUG 2020 16:07
PC Close Date & Time	12 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

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

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

Yes ☐	
PC Time stamp	13 AUG 2020 12:09
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

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

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

Yes ☐	
PC Time stamp	15 AUG 2020 12:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

Yes ☐	
PC Time stamp	16 AUG 2020 14:51
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

Yes ☐	
PC Time stamp	17 AUG 2020 12:18
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3462116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

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

US3462116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

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

US3462116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:26
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 14:21
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TYMPANIC
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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)	14 SEP 2020
What was the treatment time? (00:00-23:59)	13:50 (24 HR)
Treatment Date and Time (derived)	14 SEP 2020 13:50
Which arm was used to give treatment?	Left Arm ☐
	Right Arm ☒
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3462116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	14 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:41 (24 HR)
Collection date and time (derived)	14 SEP 2020 13:41

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:07

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:43	14 SEP 2020 13:43
Nasopharyngeal Swab 2	No		

US3462116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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

97.6 °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 SEP 2020 14:20

PC Open Date & Time

14 SEP 2020 14:10

PC Close Date & Time

14 SEP 2020 16:40

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 17:40

PC Open Date & Time

14 SEP 2020 17:35

PC Close Date & Time

15 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

16 SEP 2020 17:37

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:18

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 14:48

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 12:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

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

20 SEP 2020 17:14

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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

14 SEP 2020 14:20

PC Open Date & Time

14 SEP 2020 14:10

PC Close Date & Time

14 SEP 2020 16:40

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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

14 SEP 2020 17:40

PC Open Date & Time

14 SEP 2020 17:35

PC Close Date & Time

15 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

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

16 SEP 2020 17:38

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

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

17 SEP 2020 12:18

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

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

18 SEP 2020 14:48

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

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

19 SEP 2020 12:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

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

20 SEP 2020 17:14

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 14:20
PC Open Date & Time	14 SEP 2020 14:10
PC Close Date & Time	14 SEP 2020 16:40

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 17:40
PC Open Date & Time	14 SEP 2020 17:35
PC Close Date & Time	15 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

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

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

Yes ☐	
PC Time stamp	16 SEP 2020 17:38
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

Yes ☐	
PC Time stamp	17 SEP 2020 12:19
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

Yes ☐	
PC Time stamp	18 SEP 2020 14:49
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

Yes ☐	
PC Time stamp	19 SEP 2020 12:02
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

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 ☒

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

Yes ☐	
PC Time stamp	20 SEP 2020 17:14
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3462116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

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

US3462116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

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.

US3462116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	15:50 (24 HR)
Collection date and time (derived)	13 OCT 2020 15:50

US3462116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

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

Date and time of submission

13 OCT 2020 14:12:18

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 14:03:56

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

25 OCT 2020 12:48:47

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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	08 NOV 2020 23:04:55
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 13:34:28

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 21:27:12

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

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07 JUN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 FEB 2022 00:01

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28 FEB 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 MAR 2022 00:01

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07 MAR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 MAR 2022 00:01

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14 MAR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3462116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

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

US3462116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

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

US3462116

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462116

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:31:07

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3462116

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:31:07

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

AEID	USA-US093-2020-MRNA-1273-P30 1000003
Adverse event	CONGESTIVE HEART FAILURE
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	03 SEP 2020
Start time (00:00-23:59)	08:00 (24 HR)
AE start date and time (derived)	03 SEP 2020 08:00
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	09 SEP 2020
End time (00:00-23:59)	17:00 (24 HR)
AE End Date and Time (derived)	09 SEP 2020 17:00
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	05 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	09 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

PATIENT IS 43 YEAR OLD
WOMAN WITH SOCIAL RISK
FOR COVID-19. SHE
CONSENTED AND
RANDOMIZED ON 11AUG2020
AND TOLERATED DOSE 1
UNEVENTFULLY. SHE
DEVELOPED NEW ONSET
INCREASED DYSPNEA AND
FLUID RETENTION THAT
BECAME CLINICALLY
BOTHERSOME ON 08:00 ON
03SEP2020. SHE WENT TO
ROGUE REGIONAL MEDICAL
CENTER IN MEDFORD, OR AT
APPROXIMATELY 09:00 ON
04SEP2020, AND WAS
ADMITTED FOR NEW ONSET
CONGESTIVE HEART FAILURE
(CHF). CHF WAS CONFIRMED
ON CHEST X-RAY AND
ECHOCARDIOGRAM, AND
OTHER HEART DISEASE WAS
RULED WITH ANGIOGRAM AND
CHEST CT. PATIENT WAS
DIURESED WITH FUROSEMIDE
AND RECOVERED FULLY. SHE
WAS DISCHARGED TO HOME
ON 09SEP2020 AT ABOUT 17:00
ON NEW ORAL DIURETIC
MEDICATIONS TO PREVENT
CHF. ALL HISTORY FROM
PHONE CALL TO PATIENT ON
09SEP2020 AT 18:30. WE ARE
REPORTING THIS SAE TODAY.
SAE REPORT UPDATED
05NOV2020 BASED

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

ON HOSPITAL DISCHARGE
SUMMARY. DC SUMMARY
CONFIRMS ADMIT DATE WAS
05SEP2020 AND DC DATE
09SEP2020. PRIMARY
DIAGNOSIS WAS ACUTE CHF
THAT IMPROVED AFTER 2
LITERS DIURESIS WITH
FUROSEMIDE. ECHO
CONFIRMED LOW LVEF OF 30%
CONFIRMING SYSTOLIC CHF.

SUBJECT ALSO HAD A LEFT
HEART CATERITERISATION
TEST PERFORMED WHICH
SHOWED NORMAL CORONARY
ARTERIES. FAMILY HISTORY
WAS POSITIVE FOR (b) (6)
AND (b) (6) BOTH
DYING IN 40S WITH POSSIBLE
FAMILIAL CARDIOMYOPATHY
AND CHF. SUBJECT ALSO HAD
REMOTE HISTORY OF
METHAMPHETAMINE ABUSE
1993-2003 THAT MAY HAVE
CONTRIBUTED TO
CARDIOMYOPATHY.
THEREFORE, PATIENT SEEMS
TO HAVE A PREVIOUSLY
UNDIAGNOSED FAMILIAL
CARDIOMYOPATHY WHICH
MAY BE DO TO A) HISTORY OF
CHF IN (b) (6) AND (b) (6), B)
WEIGHT LIFTING AND
METHAMPHETAMINE ABUSE
AS TEENAGER AND YOUNG
ADULT, AND C) PATIENT ALSO

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

SEEMS TO HAVE BORDERLINE
DIABETES TYPE II THAT MAY
CONTRIBUTE TO
CARDIOMYOPATHY. SHE WAS
DISCHARGED TO HOME ON
NEW MEDS FOR
CARDIOMYOPATHY
INCLUDING 5 MEDICATIONS,
AND WITH FOLLOW-UP WITH
CARDIOLOGIST PLANNED IN
2-3 MONTHS. SAE IS UPDATED
TODAY WITH THIS
INFORMATION FROM
HOSPITAL RECORDS.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

AEID	
Adverse event	FAMILIAL CARDIOMYOPATHY
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	05 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:31:07

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

Yes ☒

No ☐

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

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

Name of Medication	SYNTHROID
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
Dose per administration	112
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 ☐

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

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 2005
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 ☒

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

Name of Medication	REQUIP
Prophylaxis	Yes ☐ No ☒
Indication	RESTLESS LEG SYNDROME
Dose per administration	2.5
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 ☐

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

	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 2007
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	OCCASIONAL HEADACHE
Dose per administration	800
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

Name of Medication	CARVEDILOL
Prophylaxis	Yes ☐ No ☒
Indication	FAMILIAL CARDIOMYOPATHY
Dose per administration	3.125
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

Name of Medication	FUROSEMIDE
Prophylaxis	Yes ☐ No ☒
Indication	FAMILIAL CARDIOMYOPATHY
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

	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)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ☒
Indication	FAMILIAL CARDIOMYOPATHY
Dose per administration	2.5
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

	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)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

Name of Medication	SPIRONOLACTONE
Prophylaxis	Yes ☐ No ☒
Indication	FAMILIAL CARDIOMYOPATHY
Dose per administration	6.25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

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) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

Name of Medication	LANTUS
Prophylaxis	Yes ☐ No ☒
Indication	TYPE II DIABETES
Dose per administration	22
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNITS
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

	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 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

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

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

	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 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

Name of Medication	ALBUTEROL
Prophylaxis	Yes ☐ No ☒
Indication	EXERTIONAL BRONCHOSPASM
Dose per administration	180
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 ☐

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

	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 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:31:07

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:31:07

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 SEP 2020	ECHOCARDIOGRAM	Adverse Event	
05 SEP 2020	CAT SCAN	Adverse Event	
04 SEP 2020	CHEST X-RAY	Adverse Event	
08 SEP 2020	ANGIOGRAM	Adverse Event	

US3462116

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:31:07

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

US3462116

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:31:07

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 ☐

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

SAEID	USA-US093-2020-MRNA-1273-P301000003
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:07

SAEID	USA-US093-2020-MRNA-1273-P301000003
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	12/SEP/2020 11:31
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

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:07

SAEID	USA-US093-2020-MRNA-1273-P301000003
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/NOV/2020 13:48
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

US3462116 (Prod: Crisor, LLC)

US3462116

Form: Participant Creation

Generated On: 26 Nov 2020 09:31:07

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3462116'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 17:14:43

US3462116

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:25:19
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:09

US3462116

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:25:19
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:14:44

US3462116

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:25:19
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:09

US3462116

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Aug 2020 19:30:09

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered (b) (6) 1977'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:14:45

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '43'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '43'	System	11 Aug 2020 19:30:48

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

Sex

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered 'Female (F)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

White

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '1'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

If race is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

Unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:07

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered '11 Aug 2020'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

US3462116

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	11 Aug 2020 19:30:48

US3462116

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 19:30:48

US3462116

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered 'Amendment 2 (2)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

US3462116

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

US3462116

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

US3462116

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

US3462116

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

US3462116

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:14:44

US3462116

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:30:54

US3462116

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:30:41
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:54

US3462116

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:31:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:30:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 01:53:45

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:56:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:56:12
Data point term sent to Coder	System	13 Aug 2020 01:55:09
User entered 'Tonsillitis'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 1981'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 1981'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '1981'	System	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '1981'	System	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 01:56:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 01:56:12
Data point term sent to Coder	System	13 Aug 2020 01:55:10
User entered 'Restless Leg Syndrome'	(b) (4), (b) (6) (b) (4) (b) (4)	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	(b) (4), (b) (6)	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2006'	System	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:48:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:48:12
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 01:56:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 01:56:12
Data point term sent to Coder	System	13 Aug 2020 01:55:10
User entered 'Occasional Headaches'	(b) (4), (b) (6)	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2000'	System	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Lymphomas Hodgkin's disease, HLT: Hodgkin's disease NEC, PT: Hodgkin's disease, LLT: Hodgkin's lymphoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 01:57:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 01:57:14
Data point term sent to Coder	System	13 Aug 2020 01:56:10
User entered 'Hodgkins Lymphoma'	(b) (4), (b) (6) (b) (4) (b) (4)	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	(b) (4), (b) (6)	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	(b) (4), (b) (6)	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2003'	System	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2004'	System	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 01:57:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 01:57:14
Data point term sent to Coder	System	13 Aug 2020 01:56:10
User entered 'Hypothyroidism'	(b) (4), (b) (6) 	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	(b) (4), (b) (6)	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2004'	System	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Ankle osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 12:44:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 12:44:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:14:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:14:43
Data point term sent to Coder	System	13 Aug 2020 01:57:12
User entered 'Right Ankle Arthritis'	(b) (4), (b) (6) (b) (4) (b) (4)	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 1997'	(b) (4), (b) (6)	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	(b) (4), (b) (6)	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '1997'	System	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2006'	System	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Ruptured intervertebral disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Sep 2020 14:00:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Sep 2020 14:00:45
Data point term sent to Coder	System	13 Aug 2020 01:57:11
User entered 'Ruptured L5'	(b) (4), (b) (6) (b) (4) (b) (4)	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 1991'	(b) (4), (b) (6)	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 1991'	(b) (4), (b) (6)	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '1991'	System	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '1991'	System	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Ruptured intervertebral disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Sep 2020 14:00:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Sep 2020 14:00:45
Data point term sent to Coder	System	13 Aug 2020 01:57:12
User entered 'Ruptured L6'	(b) (4), (b) (6) (b) (4) (b) (4)	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	(b) (4), (b) (6)	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	(b) (4), (b) (6)	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2006'	System	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2006'	System	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 01:59:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 01:59:15
Data point term sent to Coder	System	13 Aug 2020 01:58:12
User entered 'Tubal Ligation'	(b) (4), (b) (6) 	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un Nov 2005'	(b) (4), (b) (6)	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un Nov 2005'	(b) (4), (b) (6)	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Nov 2005'	System	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2005'	System	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Nov 2005'	System	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2005'	System	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ankle operation, LLT: Ankle operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 10:39:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 10:39:02
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:11:41
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Ankle joint fusion secondary to ankle arthritis note in past medical history' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 15:46:50
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:16:44
Data point term sent to Coder	System	13 Aug 2020 01:58:12
User entered 'Right Ankle Joint Fusion'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2016'	System	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2016'	System	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Lumbar discectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:00:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:00:16
Data point term sent to Coder	System	13 Aug 2020 01:59:13
User entered 'Lumbar Discectomy'	(b) (4), (b) (6) (b) (4) (b) (4)	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 1991'	(b) (4), (b) (6)	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:20:59
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 15:50:03
User entered 'UN UNK 1991' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 15:49:50
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:17:03
User entered 'un UNK 2006'	(b) (4), (b) (6)	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '1991'	System	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	04 Nov 2020 15:49:50
User entered 'Jan 2006'	System	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '1991'	System	04 Nov 2020 15:49:50
User entered '2006'	System	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:00:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:00:16
Data point term sent to Coder	System	13 Aug 2020 01:59:13
User entered 'Tonsillectomy'	(b) (4), (b) (6) 	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 1981'	(b) (4), (b) (6)	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 1981'	(b) (4), (b) (6)	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '1981'	System	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '1981'	System	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Lumbar discectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 15:51:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 15:51:25
Data point term sent to Coder	System	04 Nov 2020 15:50:40
User entered 'Lumbar Disectomy'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2006'	Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2006'	System	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2006'	System	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:27:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:27:04
Data point term sent to Coder	System	25 Nov 2020 02:26:05
User entered 'Type II Diabetes'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2019'	System	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	25 Nov 2020 02:26:03
User entered 'Exertional Bronchospasm'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '2004'	System	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '10:58'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 10:58'	System	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '173' cm	(b) (4), (b) (6)	13 Aug 2020 01:59:52
DataPoint set to visible.	System	11 Aug 2020 19:30:54

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '108' kg	(b) (4), (b) (6)	13 Aug 2020 01:59:52
DataPoint set to visible.	System	11 Aug 2020 19:30:54

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '36.08540'	System	16 Sep 2020 23:51:55
User entered '36.1'	System	13 Aug 2020 01:59:52
DataPoint set to visible.	System	11 Aug 2020 19:30:54

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	13 Aug 2020 01:59:52
DataPoint set to visible.	System	11 Aug 2020 19:30:54

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered '97.5' F	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered 'Other (Other)'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered 'Tympanic'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered '90'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered '16'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered '140'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered '84'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:00:05

US3462116

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

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)	24 Sep 2020 11:28:22
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 21:15:06
User entered '11 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 02:00:05

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:31:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:31:07

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:31:07

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:31:07

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:31:07

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	13 Aug 2020 02:00:50
User entered 'un Nov 2005' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 02:00:50
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	13 Aug 2020 02:00:31
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:31:07

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:31:07

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:31:07

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:07

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:29:01
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:26:53
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:13

US3462116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:13

US3462116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:13

US3462116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Aug 2020 19:31:13

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 18:29:15

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:07

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 03:36:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:36:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 18:29:15
User entered '103130' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 18:29:15

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 18:29:15

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:59

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:59

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:59

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:07

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:59

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:07

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:59

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 20:32:54
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:32:38

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:07

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '173' cm	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '108' kg	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:07

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '173' cm	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '108' kg	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '10:58'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 10:58'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '90'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:07

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '173' cm	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '108' kg	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

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 12:13:01
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).		13 Aug 2020 02:04:17
User entered '12:53'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:53'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '95'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '152'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '92'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:04:54

US3462116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 02:04:54

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '12:22'	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:22'	System	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	10 Nov 2020 02:34:17
User entered 'Left Arm (LEFT ARM)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:05:12

US3462116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 02:05:12

US3462116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:50'	(b) (4), (b) (6)	13 Aug 2020 02:05:12

US3462116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:50'	System	13 Aug 2020 02:05:12

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:52'	(b) (4), (b) (6)	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:52'	System	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:33:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:33:13
User entered '11:52'	(b) (4), (b) (6)	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:33:13
User entered '11 Aug 2020 11:52'	System	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:05:48

US3462116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 02:05:48

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:55:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ed9b08e9-5f5c-40c2-b116-07a66b66abb9'	System	11 Aug 2020 19:55:24
User entered 'Yes (Y)'	System	11 Aug 2020 19:55:24

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:55:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ed9b08e9-5f5c-40c2-b116-07a66b66abb9'	System	11 Aug 2020 19:55:24
User entered '93.7'	System	11 Aug 2020 19:55:24

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:55:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ed9b08e9-5f5c-40c2-b116-07a66b66abb9'	System	11 Aug 2020 19:55:24
User entered 'No (N)'	System	11 Aug 2020 19:55:24

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:55:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ed9b08e9-5f5c-40c2-b116-07a66b66abb9'	System	11 Aug 2020 19:55:24
User entered '11 Aug 2020 12:55'	System	11 Aug 2020 19:55:24

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:42'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 15:12'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:09:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '10135816-9a8a-4172-948a-beb77a165989'	System	11 Aug 2020 23:10:25
User entered 'Yes (Y)'	System	11 Aug 2020 23:10:25

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '10135816-9a8a-4172-948a-beb77a165989'	System	11 Aug 2020 23:10:25
User entered '97.4'	System	11 Aug 2020 23:10:25

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '10135816-9a8a-4172-948a-beb77a165989'	System	11 Aug 2020 23:10:25
User entered 'No (N)'	System	11 Aug 2020 23:10:25

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '10135816-9a8a-4172-948a-beb77a165989'	System	11 Aug 2020 23:10:25
User entered '11 Aug 2020 16:10'	System	11 Aug 2020 23:10:25

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 16:07'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 2'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:40:48', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '29389baf-3cfe-43d0-8ef1-66e88e5cc930'	System	12 Aug 2020 19:41:08
User entered 'Yes (Y)'	System	12 Aug 2020 19:41:08

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:40:56', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '29389baf-3cfe-43d0-8ef1-66e88e5cc930'	System	12 Aug 2020 19:41:08
User entered '97.4'	System	12 Aug 2020 19:41:08

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '29389baf-3cfe-43d0-8ef1-66e88e5cc930'	System	12 Aug 2020 19:41:08
User entered 'No (N)'	System	12 Aug 2020 19:41:08

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:04', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '29389baf-3cfe-43d0-8ef1-66e88e5cc930'	System	12 Aug 2020 19:41:08
User entered '12 Aug 2020 12:41'	System	12 Aug 2020 19:41:08

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 3'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '964bea8c-a044-4bae-b7a7-15d179e356be'	System	13 Aug 2020 19:08:33
User entered 'Yes (Y)'	System	13 Aug 2020 19:08:33

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '964bea8c-a044-4bae-b7a7-15d179e356be'	System	13 Aug 2020 19:08:33
User entered '98.0'	System	13 Aug 2020 19:08:33

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '964bea8c-a044-4bae-b7a7-15d179e356be'	System	13 Aug 2020 19:08:33
User entered 'No (N)'	System	13 Aug 2020 19:08:33

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:32', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '964bea8c-a044-4bae-b7a7-15d179e356be'	System	13 Aug 2020 19:08:33
User entered '13 Aug 2020 12:08'	System	13 Aug 2020 19:08:33

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 4'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:40', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ba9b18b9-230d-48e4-9697-155c59321959'	System	14 Aug 2020 21:59:53
User entered 'Yes (Y)'	System	14 Aug 2020 21:59:53

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:45', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ba9b18b9-230d-48e4-9697-155c59321959'	System	14 Aug 2020 21:59:53
User entered '97.5'	System	14 Aug 2020 21:59:53

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ba9b18b9-230d-48e4-9697-155c59321959'	System	14 Aug 2020 21:59:53
User entered 'No (N)'	System	14 Aug 2020 21:59:53

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:50', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ba9b18b9-230d-48e4-9697-155c59321959'	System	14 Aug 2020 21:59:53
User entered '14 Aug 2020 14:59'	System	14 Aug 2020 21:59:53

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 5'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:36', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1f17371a-1836-40ec-b937-b85eb76b79c7'	System	15 Aug 2020 19:00:49
User entered 'Yes (Y)'	System	15 Aug 2020 19:00:49

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:41', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1f17371a-1836-40ec-b937-b85eb76b79c7'	System	15 Aug 2020 19:00:49
User entered '98.0'	System	15 Aug 2020 19:00:49

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1f17371a-1836-40ec-b937-b85eb76b79c7'	System	15 Aug 2020 19:00:49
User entered 'No (N)'	System	15 Aug 2020 19:00:49

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1f17371a-1836-40ec-b937-b85eb76b79c7'	System	15 Aug 2020 19:00:49
User entered '15 Aug 2020 12:00'	System	15 Aug 2020 19:00:49

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 6'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:50:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'acf93b17-d577-49c7-b5a9-71e5b0b5d9d5'	System	16 Aug 2020 21:51:10
User entered 'Yes (Y)'	System	16 Aug 2020 21:51:10

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:03', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'acf93b17-d577-49c7-b5a9-71e5b0b5d9d5'	System	16 Aug 2020 21:51:10
User entered '97.6'	System	16 Aug 2020 21:51:10

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'acf93b17-d577-49c7-b5a9-71e5b0b5d9d5'	System	16 Aug 2020 21:51:10
User entered 'No (N)'	System	16 Aug 2020 21:51:10

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:07', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'acf93b17-d577-49c7-b5a9-71e5b0b5d9d5'	System	16 Aug 2020 21:51:10
User entered '16 Aug 2020 14:51'	System	16 Aug 2020 21:51:10

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 7'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:17:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f7424613-1d4a-4a37-9860-f8c9c77294ae'	System	17 Aug 2020 19:18:16
User entered 'Yes (Y)'	System	17 Aug 2020 19:18:16

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f7424613-1d4a-4a37-9860-f8c9c77294ae'	System	17 Aug 2020 19:18:16
User entered '97.8'	System	17 Aug 2020 19:18:16

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:07', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f7424613-1d4a-4a37-9860-f8c9c77294ae'	System	17 Aug 2020 19:18:16
User entered 'No (N)'	System	17 Aug 2020 19:18:16

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:10', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f7424613-1d4a-4a37-9860-f8c9c77294ae'	System	17 Aug 2020 19:18:16
User entered '17 Aug 2020 12:18'	System	17 Aug 2020 19:18:16

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-11T12:56:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'af33352b-d932-4ae8-a906-605493471ec7'	System	11 Aug 2020 19:56:42
User entered 'None (1)'	System	11 Aug 2020 19:56:42

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'af33352b-d932-4ae8-a906-605493471ec7'	System	11 Aug 2020 19:56:42
User entered 'No (N)'	System	11 Aug 2020 19:56:42

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:24', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'af33352b-d932-4ae8-a906-605493471ec7'	System	11 Aug 2020 19:56:42
User entered 'No (N)'	System	11 Aug 2020 19:56:42

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-11T12:56:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'af33352b-d932-4ae8-a906-605493471ec7'	System	11 Aug 2020 19:56:42
User entered 'None (1)'	System	11 Aug 2020 19:56:42

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:37', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'af33352b-d932-4ae8-a906-605493471ec7'	System	11 Aug 2020 19:56:42
User entered '11 Aug 2020 12:56'	System	11 Aug 2020 19:56:42

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:42'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 15:12'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-11T16:10:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:50', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered 'No (N)'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered 'Yes (Y)'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:11:52', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d' User entered '4'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-11T16:12:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered 'None (1)'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered '11 Aug 2020 16:12'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 16:07'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 2'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-12T12:41:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered 'No (N)'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered 'Yes (Y)'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03' User entered '4'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-12T12:41:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered 'None (1)'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:27', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered '12 Aug 2020 12:41'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 3'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-13T12:08:37', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered 'None (1)'	System	13 Aug 2020 19:08:53

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:40', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered 'No (N)'	System	13 Aug 2020 19:08:53

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:43', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered 'Yes (Y)'	System	13 Aug 2020 19:08:53

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9' User entered '3'	System	13 Aug 2020 19:08:53

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-13T12:08:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered 'None (1)'	System	13 Aug 2020 19:08:53

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:51', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered '13 Aug 2020 12:08'	System	13 Aug 2020 19:08:53

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 4'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-14T14:59:54', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '252a7445-17a3-463c-ad8b-35f0f14e5d06'	System	14 Aug 2020 22:00:10
User entered 'None (1)'	System	14 Aug 2020 22:00:10

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '252a7445-17a3-463c-ad8b-35f0f14e5d06'	System	14 Aug 2020 22:00:10
User entered 'No (N)'	System	14 Aug 2020 22:00:10

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '252a7445-17a3-463c-ad8b-35f0f14e5d06'	System	14 Aug 2020 22:00:10
User entered 'No (N)'	System	14 Aug 2020 22:00:10

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-14T15:00:02', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '252a7445-17a3-463c-ad8b-35f0f14e5d06'	System	14 Aug 2020 22:00:10
User entered 'None (1)'	System	14 Aug 2020 22:00:10

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:04', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '252a7445-17a3-463c-ad8b-35f0f14e5d06'	System	14 Aug 2020 22:00:10
User entered '14 Aug 2020 15:00'	System	14 Aug 2020 22:00:10

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 5'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-15T12:00:52', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'bc67f1ec-9900-4237-8e93-0b918f8f773f'	System	15 Aug 2020 19:01:07
User entered 'None (1)'	System	15 Aug 2020 19:01:07

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:54', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'bc67f1ec-9900-4237-8e93-0b918f8f773f'	System	15 Aug 2020 19:01:07
User entered 'No (N)'	System	15 Aug 2020 19:01:07

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'bc67f1ec-9900-4237-8e93-0b918f8f773f'	System	15 Aug 2020 19:01:07
User entered 'No (N)'	System	15 Aug 2020 19:01:07

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-15T12:00:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'bc67f1ec-9900-4237-8e93-0b918f8f773f'	System	15 Aug 2020 19:01:07
User entered 'None (1)'	System	15 Aug 2020 19:01:07

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'bc67f1ec-9900-4237-8e93-0b918f8f773f'	System	15 Aug 2020 19:01:07
User entered '15 Aug 2020 12:01'	System	15 Aug 2020 19:01:07

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 6'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-16T14:51:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '94aa7600-6e65-4f3e-9933-aa926ae9676d'	System	16 Aug 2020 21:51:23
User entered 'None (1)'	System	16 Aug 2020 21:51:23

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:13', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '94aa7600-6e65-4f3e-9933-aa926ae9676d'	System	16 Aug 2020 21:51:23
User entered 'No (N)'	System	16 Aug 2020 21:51:23

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '94aa7600-6e65-4f3e-9933-aa926ae9676d'	System	16 Aug 2020 21:51:23
User entered 'No (N)'	System	16 Aug 2020 21:51:23

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-16T14:51:16', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '94aa7600-6e65-4f3e-9933-aa926ae9676d'	System	16 Aug 2020 21:51:23
User entered 'None (1)'	System	16 Aug 2020 21:51:23

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '94aa7600-6e65-4f3e-9933-aa926ae9676d'	System	16 Aug 2020 21:51:23
User entered '16 Aug 2020 14:51'	System	16 Aug 2020 21:51:23

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 7'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-17T12:18:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1215a8ae-c2cb-4812-84c2-75b2051adc3d'	System	17 Aug 2020 19:18:27
User entered 'None (1)'	System	17 Aug 2020 19:18:27

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:17', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1215a8ae-c2cb-4812-84c2-75b2051adc3d'	System	17 Aug 2020 19:18:27
User entered 'No (N)'	System	17 Aug 2020 19:18:27

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1215a8ae-c2cb-4812-84c2-75b2051adc3d'	System	17 Aug 2020 19:18:27
User entered 'No (N)'	System	17 Aug 2020 19:18:27

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-17T12:18:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1215a8ae-c2cb-4812-84c2-75b2051adc3d'	System	17 Aug 2020 19:18:27
User entered 'None (1)'	System	17 Aug 2020 19:18:27

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1215a8ae-c2cb-4812-84c2-75b2051adc3d'	System	17 Aug 2020 19:18:27
User entered '17 Aug 2020 12:18'	System	17 Aug 2020 19:18:27

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:50', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:52', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:58', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-11T12:57:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'No (N)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:57:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered '11 Aug 2020 12:57'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:42'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 15:12'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:27', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-11T16:12:33', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'No (N)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:40', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered '11 Aug 2020 16:12'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 16:07'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 2'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:33', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:36', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:38', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:41', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:43', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-12T12:41:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'No (N)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered '12 Aug 2020 12:41'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 3'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:58', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:09:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:09:02', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:09:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-13T12:09:07', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'No (N)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:09:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered '13 Aug 2020 12:09'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 4'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:10', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:13', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:16', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-14T15:00:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'No (N)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered '14 Aug 2020 15:00'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 5'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:06', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:10', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:13', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-15T12:01:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'No (N)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered '15 Aug 2020 12:01'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 6'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:23', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-16T14:51:33', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'No (N)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:35', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered '16 Aug 2020 14:51'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 7'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:33', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:34', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-08-17T12:18:36', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'No (N)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:38', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered '17 Aug 2020 12:18'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	08 Sep 2020 16:14:37

US3462116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Sep 2020 16:15:14
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	08 Sep 2020 16:15:14
User entered '18 Aug 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4) [REDACTED]	08 Sep 2020 16:15:14
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Sep 2020 16:14:37
User entered '25 Aug 2020'	Danuel Hamlin (b) (4) [REDACTED]	08 Sep 2020 16:14:37

US3462116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	08 Sep 2020 16:14:37

US3462116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	08 Sep 2020 16:14:37

US3462116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	08 Sep 2020 16:15:23

US3462116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:15:23

US3462116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	08 Sep 2020 16:15:51

US3462116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Danuel Hamlin (b) (4)	08 Sep 2020 16:15:51

US3462116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	08 Sep 2020 16:15:51

US3462116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	08 Sep 2020 16:15:51

US3462116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	08 Sep 2020 16:16:08

US3462116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:16:08

US3462116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	08 Sep 2020 16:17:54

US3462116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Danuel Hamlin (b) (4)	08 Sep 2020 16:17:54

US3462116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	08 Sep 2020 16:17:54

US3462116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	08 Sep 2020 16:17:54

US3462116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	08 Sep 2020 16:18:04

US3462116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 16:18:04

US3462116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 02:33:14
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Added' (Site from DM).	Danuel Hamlin (b) (4)	09 Nov 2020 08:42:36
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:29:12
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:06

US3462116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:06

US3462116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:06

US3462116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	14 Sep 2020 21:15:06

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '13:26'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 13:26'	System	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '16'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '14:21'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:21'	System	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Tympanic'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '88'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '14'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '120'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '13:50'	Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 13:50'	System	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 15:11:38
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'IP was administered in Right Arm at both visits.' (Site from System).	Danuel Hamlin (b) (4)	10 Nov 2020 02:33:54
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	14 Sep 2020 21:16:23
User entered 'Right Arm (RIGHT ARM)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:30

US3462116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:30

US3462116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:41'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:30

US3462116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 13:41'	System	14 Sep 2020 21:17:30

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:43'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 13:43'	System	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:34:53
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:34:53
User entered '13:43'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:34:53
User entered '14 Sep 2020 13:43'	System	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:18:00

US3462116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 21:18:00

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:19:41', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b0e8b846-6288-4f97-a180-740e76c8b909'	System	14 Sep 2020 21:20:14
User entered 'Yes (Y)'	System	14 Sep 2020 21:20:14

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:19:53', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b0e8b846-6288-4f97-a180-740e76c8b909'	System	14 Sep 2020 21:20:14
User entered '97.6'	System	14 Sep 2020 21:20:14

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:19:56', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b0e8b846-6288-4f97-a180-740e76c8b909'	System	14 Sep 2020 21:20:14
User entered 'No (N)'	System	14 Sep 2020 21:20:14

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b0e8b846-6288-4f97-a180-740e76c8b909'	System	14 Sep 2020 21:20:14
User entered '14 Sep 2020 14:20'	System	14 Sep 2020 21:20:14

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:10'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 16:40'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:39:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '5953f1e7-dc00-4b06-a9d3-0bf12260890e'	System	15 Sep 2020 00:40:11
User entered 'Yes (Y)'	System	15 Sep 2020 00:40:11

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '5953f1e7-dc00-4b06-a9d3-0bf12260890e'	System	15 Sep 2020 00:40:11
User entered '97.0'	System	15 Sep 2020 00:40:11

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:03', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '5953f1e7-dc00-4b06-a9d3-0bf12260890e'	System	15 Sep 2020 00:40:11
User entered 'No (N)'	System	15 Sep 2020 00:40:11

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:06', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '5953f1e7-dc00-4b06-a9d3-0bf12260890e'	System	15 Sep 2020 00:40:11
User entered '14 Sep 2020 17:40'	System	15 Sep 2020 00:40:11

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 17:35'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 2'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 3'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:43', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40571f9d-1b96-4dfa-870f-a5a4eafc1558'	System	17 Sep 2020 00:37:57
User entered 'Yes (Y)'	System	17 Sep 2020 00:37:57

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40571f9d-1b96-4dfa-870f-a5a4eafc1558'	System	17 Sep 2020 00:37:57
User entered '97.5'	System	17 Sep 2020 00:37:57

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:50', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40571f9d-1b96-4dfa-870f-a5a4eafc1558'	System	17 Sep 2020 00:37:57
User entered 'No (N)'	System	17 Sep 2020 00:37:57

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:53', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40571f9d-1b96-4dfa-870f-a5a4eafc1558'	System	17 Sep 2020 00:37:57
User entered '16 Sep 2020 17:37'	System	17 Sep 2020 00:37:57

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 4'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'd931564d-77a9-4600-92bd-ffdf44da8c36'	System	17 Sep 2020 19:18:44
User entered 'Yes (Y)'	System	17 Sep 2020 19:18:44

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:32', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'd931564d-77a9-4600-92bd-ffdf44da8c36'	System	17 Sep 2020 19:18:44
User entered '97.8'	System	17 Sep 2020 19:18:44

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:36', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'd931564d-77a9-4600-92bd-ffdf44da8c36'	System	17 Sep 2020 19:18:44
User entered 'No (N)'	System	17 Sep 2020 19:18:44

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:38', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'd931564d-77a9-4600-92bd-ffdf44da8c36'	System	17 Sep 2020 19:18:44
User entered '17 Sep 2020 12:18'	System	17 Sep 2020 19:18:44

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 5'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:16', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '36941127-2008-4693-a40f-67940f942168'	System	18 Sep 2020 21:48:32
User entered 'Yes (Y)'	System	18 Sep 2020 21:48:32

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '36941127-2008-4693-a40f-67940f942168'	System	18 Sep 2020 21:48:32
User entered '97.0'	System	18 Sep 2020 21:48:32

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:23', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '36941127-2008-4693-a40f-67940f942168'	System	18 Sep 2020 21:48:32
User entered 'No (N)'	System	18 Sep 2020 21:48:32

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '36941127-2008-4693-a40f-67940f942168'	System	18 Sep 2020 21:48:32
User entered '18 Sep 2020 14:48'	System	18 Sep 2020 21:48:32

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 6'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:01:51', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2bc18dd5-ae11-430f-9a8b-919d8b1d8f94'	System	19 Sep 2020 19:02:07
User entered 'Yes (Y)'	System	19 Sep 2020 19:02:07

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:01:58', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2bc18dd5-ae11-430f-9a8b-919d8b1d8f94'	System	19 Sep 2020 19:02:07
User entered '97.8'	System	19 Sep 2020 19:02:07

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2bc18dd5-ae11-430f-9a8b-919d8b1d8f94'	System	19 Sep 2020 19:02:07
User entered 'No (N)'	System	19 Sep 2020 19:02:07

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:04', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2bc18dd5-ae11-430f-9a8b-919d8b1d8f94'	System	19 Sep 2020 19:02:07
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 19:02:07

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 7'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'fc881263-6e6a-4240-ba93-392b353de396'	System	21 Sep 2020 00:14:18
User entered 'Yes (Y)'	System	21 Sep 2020 00:14:18

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'fc881263-6e6a-4240-ba93-392b353de396'	System	21 Sep 2020 00:14:18
User entered '98.0'	System	21 Sep 2020 00:14:18

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'fc881263-6e6a-4240-ba93-392b353de396'	System	21 Sep 2020 00:14:18
User entered 'No (N)'	System	21 Sep 2020 00:14:18

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'fc881263-6e6a-4240-ba93-392b353de396'	System	21 Sep 2020 00:14:18
User entered '20 Sep 2020 17:14'	System	21 Sep 2020 00:14:18

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-14T14:20:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'eda360d9-8a9b-4c76-9de0-3f5da48538d9'	System	14 Sep 2020 21:20:28
User entered 'None (1)'	System	14 Sep 2020 21:20:28

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:17', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'eda360d9-8a9b-4c76-9de0-3f5da48538d9'	System	14 Sep 2020 21:20:28
User entered 'No (N)'	System	14 Sep 2020 21:20:28

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:19', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'eda360d9-8a9b-4c76-9de0-3f5da48538d9'	System	14 Sep 2020 21:20:28
User entered 'No (N)'	System	14 Sep 2020 21:20:28

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-14T14:20:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'eda360d9-8a9b-4c76-9de0-3f5da48538d9'	System	14 Sep 2020 21:20:28
User entered 'None (1)'	System	14 Sep 2020 21:20:28

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:24', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'eda360d9-8a9b-4c76-9de0-3f5da48538d9'	System	14 Sep 2020 21:20:28
User entered '14 Sep 2020 14:20'	System	14 Sep 2020 21:20:28

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:10'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 16:40'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-14T17:40:10', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '96642bfa-7796-4476-a268-e056fb9edc81'	System	15 Sep 2020 00:40:23
User entered 'None (1)'	System	15 Sep 2020 00:40:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '96642bfa-7796-4476-a268-e056fb9edc81'	System	15 Sep 2020 00:40:23
User entered 'No (N)'	System	15 Sep 2020 00:40:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '96642bfa-7796-4476-a268-e056fb9edc81'	System	15 Sep 2020 00:40:23
User entered 'No (N)'	System	15 Sep 2020 00:40:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-14T17:40:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '96642bfa-7796-4476-a268-e056fb9edc81'	System	15 Sep 2020 00:40:23
User entered 'None (1)'	System	15 Sep 2020 00:40:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '96642bfa-7796-4476-a268-e056fb9edc81'	System	15 Sep 2020 00:40:23
User entered '14 Sep 2020 17:40'	System	15 Sep 2020 00:40:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 17:35'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 2'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 3'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-16T17:37:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f510e5e6-e016-4e76-84a3-063596462cec'	System	17 Sep 2020 00:38:11
User entered 'None (1)'	System	17 Sep 2020 00:38:11

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f510e5e6-e016-4e76-84a3-063596462cec'	System	17 Sep 2020 00:38:11
User entered 'No (N)'	System	17 Sep 2020 00:38:11

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f510e5e6-e016-4e76-84a3-063596462cec'	System	17 Sep 2020 00:38:11
User entered 'No (N)'	System	17 Sep 2020 00:38:11

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-16T17:38:02', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f510e5e6-e016-4e76-84a3-063596462cec'	System	17 Sep 2020 00:38:11
User entered 'None (1)'	System	17 Sep 2020 00:38:11

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f510e5e6-e016-4e76-84a3-063596462cec'	System	17 Sep 2020 00:38:11
User entered '16 Sep 2020 17:38'	System	17 Sep 2020 00:38:11

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 4'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-17T12:18:42', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3870f970-dbb4-4d1f-9b69-1073006e65b4'	System	17 Sep 2020 19:18:59
User entered 'None (1)'	System	17 Sep 2020 19:18:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3870f970-dbb4-4d1f-9b69-1073006e65b4'	System	17 Sep 2020 19:18:59
User entered 'No (N)'	System	17 Sep 2020 19:18:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3870f970-dbb4-4d1f-9b69-1073006e65b4'	System	17 Sep 2020 19:18:59
User entered 'No (N)'	System	17 Sep 2020 19:18:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-17T12:18:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3870f970-dbb4-4d1f-9b69-1073006e65b4'	System	17 Sep 2020 19:18:59
User entered 'None (1)'	System	17 Sep 2020 19:18:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3870f970-dbb4-4d1f-9b69-1073006e65b4'	System	17 Sep 2020 19:18:59
User entered '17 Sep 2020 12:18'	System	17 Sep 2020 19:18:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 5'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-18T14:48:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b7086360-5e91-4546-a807-75a1a32d10fd'	System	18 Sep 2020 21:48:47
User entered 'None (1)'	System	18 Sep 2020 21:48:47

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:34', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b7086360-5e91-4546-a807-75a1a32d10fd'	System	18 Sep 2020 21:48:47
User entered 'No (N)'	System	18 Sep 2020 21:48:47

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:37', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b7086360-5e91-4546-a807-75a1a32d10fd'	System	18 Sep 2020 21:48:47
User entered 'No (N)'	System	18 Sep 2020 21:48:47

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-18T14:48:39', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b7086360-5e91-4546-a807-75a1a32d10fd'	System	18 Sep 2020 21:48:47
User entered 'None (1)'	System	18 Sep 2020 21:48:47

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:42', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b7086360-5e91-4546-a807-75a1a32d10fd'	System	18 Sep 2020 21:48:47
User entered '18 Sep 2020 14:48'	System	18 Sep 2020 21:48:47

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 6'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-19T12:02:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '7a38c54b-9f89-4a16-b796-772fac987461'	System	19 Sep 2020 19:02:20
User entered 'None (1)'	System	19 Sep 2020 19:02:20

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '7a38c54b-9f89-4a16-b796-772fac987461'	System	19 Sep 2020 19:02:20
User entered 'No (N)'	System	19 Sep 2020 19:02:20

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:13', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '7a38c54b-9f89-4a16-b796-772fac987461'	System	19 Sep 2020 19:02:20
User entered 'No (N)'	System	19 Sep 2020 19:02:20

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-19T12:02:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '7a38c54b-9f89-4a16-b796-772fac987461'	System	19 Sep 2020 19:02:20
User entered 'None (1)'	System	19 Sep 2020 19:02:20

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:17', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '7a38c54b-9f89-4a16-b796-772fac987461'	System	19 Sep 2020 19:02:20
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 19:02:20

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 7'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-20T17:14:16', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '129a708b-0432-4200-b1c9-fb1327f345e0'	System	21 Sep 2020 00:14:36
User entered 'None (1)'	System	21 Sep 2020 00:14:36

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:19', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '129a708b-0432-4200-b1c9-fb1327f345e0'	System	21 Sep 2020 00:14:36
User entered 'No (N)'	System	21 Sep 2020 00:14:36

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '129a708b-0432-4200-b1c9-fb1327f345e0'	System	21 Sep 2020 00:14:36
User entered 'No (N)'	System	21 Sep 2020 00:14:36

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-20T17:14:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '129a708b-0432-4200-b1c9-fb1327f345e0'	System	21 Sep 2020 00:14:36
User entered 'None (1)'	System	21 Sep 2020 00:14:36

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '129a708b-0432-4200-b1c9-fb1327f345e0'	System	21 Sep 2020 00:14:36
User entered '20 Sep 2020 17:14'	System	21 Sep 2020 00:14:36

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:27', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:30', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:32', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:35', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:37', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-14T14:20:45', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'No (N)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered '14 Sep 2020 14:20'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:10'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 16:40'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:23', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:27', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-14T17:40:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'No (N)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:32', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered '14 Sep 2020 17:40'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 17:35'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 2'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 3'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:10', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:13', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-16T17:38:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'No (N)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:17', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered '16 Sep 2020 17:38'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 4'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:52', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:54', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:56', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:58', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-17T12:19:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'No (N)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:19:02', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered '17 Sep 2020 12:19'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 5'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:48', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:51', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:53', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:56', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-18T14:48:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'No (N)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:49:02', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered '18 Sep 2020 14:49'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 6'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:24', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-19T12:02:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'No (N)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 7'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:32', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:34', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:35', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:37', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-09-20T17:14:41', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'No (N)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:43', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered '20 Sep 2020 17:14'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:08:24

US3462116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Danuel Hamlin (b) (4)	04 Nov 2020 15:08:24

US3462116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:08:24

US3462116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	04 Nov 2020 15:08:24

US3462116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:08:30

US3462116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 15:08:30

US3462116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:08:55

US3462116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Danuel Hamlin (b) (4)	04 Nov 2020 15:08:55

US3462116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:08:55

US3462116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	04 Nov 2020 15:08:55

US3462116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:09:01

US3462116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 15:09:01

US3462116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:09:17

US3462116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '05 Oct 2020'	Danuel Hamlin (b) (4)	04 Nov 2020 15:09:17

US3462116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:09:17

US3462116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	04 Nov 2020 15:09:17

US3462116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 19:32:39

US3462116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 19:32:39

US3462116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 19:32:54

US3462116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Danuel Hamlin (b) (4)	05 Nov 2020 19:32:54

US3462116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	05 Nov 2020 19:32:54

US3462116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Nov 2020 19:32:54

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:08

US3462116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:08

US3462116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:28

US3462116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:28

US3462116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:50'	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:28

US3462116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 15:50'	System	05 Nov 2020 19:33:28

US3462116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 19:33:33

US3462116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 19:33:33

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 64'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[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 (828bc5fe3770f41d)', Time: '2020-10-13T14:12:07', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '97137beb-fc64-41da-bb8a-f468fc5e35e1'	System	13 Oct 2020 21:12:23
User entered 'No (N)'	System	13 Oct 2020 21:12:23

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-10-13T14:12:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '97137beb-fc64-41da-bb8a-f468fc5e35e1'	System	13 Oct 2020 21:12:23
User entered 'No (N)'	System	13 Oct 2020 21:12:23

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-13T14:12:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '97137beb-fc64-41da-bb8a-f468fc5e35e1'	System	13 Oct 2020 21:12:23
User entered '13 Oct 2020 14:12:18'	System	13 Oct 2020 21:12:23

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 71'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[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 (828bc5fe3770f41d)', Time: '2020-10-19T14:03:50', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '62665bfa-98f0-4e6d-bc00-99c80f8affa0'	System	19 Oct 2020 21:04:30
User entered 'No (N)'	System	19 Oct 2020 21:04:30

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-10-19T14:03:53', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '62665bfa-98f0-4e6d-bc00-99c80f8affa0'	System	19 Oct 2020 21:04:30
User entered 'No (N)'	System	19 Oct 2020 21:04:30

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-19T14:03:56', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '62665bfa-98f0-4e6d-bc00-99c80f8affa0'	System	19 Oct 2020 21:04:30
User entered '19 Oct 2020 14:03:56'	System	19 Oct 2020 21:04:30

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 78'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[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 (828bc5fe3770f41d)', Time: '2020-10-25T12:48:41', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3eebf8b5-b912-4ba5-855e-63e1a3e9b8bc'	System	25 Oct 2020 19:48:53
User entered 'No (N)'	System	25 Oct 2020 19:48:53

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-10-25T12:48:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3eebf8b5-b912-4ba5-855e-63e1a3e9b8bc'	System	25 Oct 2020 19:48:53
User entered 'No (N)'	System	25 Oct 2020 19:48:53

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-25T12:48:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3eebf8b5-b912-4ba5-855e-63e1a3e9b8bc'	System	25 Oct 2020 19:48:53
User entered '25 Oct 2020 12:48:47'	System	25 Oct 2020 19:48:53

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 92'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-11-08T23:04:48', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'efe4ff86-1621-4184-b1e3-41eaac66f7c5'	System	09 Nov 2020 07:04:58
User entered 'No (N)'	System	09 Nov 2020 07:04:58

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-11-08T23:04:51', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'efe4ff86-1621-4184-b1e3-41eaac66f7c5'	System	09 Nov 2020 07:04:58
User entered 'No (N)'	System	09 Nov 2020 07:04:58

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-08T23:04:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'efe4ff86-1621-4184-b1e3-41eaac66f7c5'	System	09 Nov 2020 07:04:58
User entered '08 Nov 2020 23:04:55'	System	09 Nov 2020 07:04:58

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 99'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

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 (828bc5fe3770f41d)', Time: '2020-11-17T13:34:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '6fe7f955-fc06-4086-aa26-4639abae0db'	System	17 Nov 2020 21:34:32
User entered 'No (N)'	System	17 Nov 2020 21:34:32

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-11-17T13:34:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '6fe7f955-fc06-4086-aa26-4639abae0db'	System	17 Nov 2020 21:34:32
User entered 'No (N)'	System	17 Nov 2020 21:34:32

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-17T13:34:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '6fe7f955-fc06-4086-aa26-4639abae0db'	System	17 Nov 2020 21:34:32
User entered '17 Nov 2020 13:34:28'	System	17 Nov 2020 21:34:32

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[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 (828bc5fe3770f41d)', Time: '2020-11-21T21:27:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3a63a66a-8a02-4924-b0f4-6353edec0f63'	System	22 Nov 2020 05:31:24
User entered 'No (N)'	System	22 Nov 2020 05:31:24

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-11-21T21:27:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3a63a66a-8a02-4924-b0f4-6353edec0f63'	System	22 Nov 2020 05:31:24
User entered 'No (N)'	System	22 Nov 2020 05:31:24

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-21T21:27:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3a63a66a-8a02-4924-b0f4-6353edec0f63'	System	22 Nov 2020 05:31:24
User entered '21 Nov 2020 21:27:12'	System	22 Nov 2020 05:31:24

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:56:16

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 23:18:40

US3462116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 10:01:35
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	(b) (4), (b) (6)	17 Nov 2020 23:18:55
answered with 'Confirmed.' (Site from System).		
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Nov 2020 23:18:40
User entered '05 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 23:18:40

US3462116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Nov 2020 23:18:40

US3462116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 23:18:40

US3462116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 23:19:04

US3462116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 23:19:04

US3462116

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:31:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:48:17
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:17:17

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:27
User entered 'USA-US093-2020-mRNA-1273-P301000003'	System	12 Sep 2020 15:31:11
User entered 'New'	(b) (4), (b) (6)	12 Sep 2020 15:31:11

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 22:25:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 22:25:51
Data point term sent to Coder	System	10 Sep 2020 22:24:50
User entered 'Congestive Heart Failure'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:51:54
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	14 Sep 2020 21:16:23
User entered '03 Sep 2020'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:03:00
	(b) (4), (b) (6)	05 Nov 2020 23:20:26
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Confirmed. Time is correct' (Site from System).	Danuel Hamlin (b) (4)	04 Nov 2020 15:36:35
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	10 Sep 2020 22:23:53
User entered '08:00'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 08:00'	System	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '09 Sep 2020'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:03:05
	(b) (4), (b) (6)	05 Nov 2020 23:20:26
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'Confirmed. Time is correct' (Site from System).	Danuel Hamlin (b) (4)	04 Nov 2020 15:36:45
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	10 Sep 2020 22:23:53
User entered '17:00'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 17:00'	System	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Grade 4 (Grade 4)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '1'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '05 Sep 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	05 Nov 2020 19:57:42
User entered '04 Sep 2020'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '09 Sep 2020'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'None (NONE)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '1'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '1'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if concomitant medication indications of "type II diabetes" and "exertional bronchospasm" should be added as medical history.' answered with 'Added' (Site from Safety).	Danuel Hamlin (b) (4)	25 Nov 2020 02:23:21
User opened query 'PV Query: Please confirm if concomitant medication indications of "type II diabetes" and "exertional bronchospasm" should be added as medical history.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:55:48
User closed query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 15:13:19
User closed query 'PV Query: Please provide echocardiogram results.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:12:29
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:12:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
Query 'PV Query: Please provide echocardiogram results.' answered with 'Echocardiogram apparently showed generalized cardiomyopathy and low ejection fraction, with LVEF of 30%. ' (Site from Safety).	Danuel Hamlin (b) (4)	05 Nov 2020 20:14:53
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 PCR test was negative done on about 05SEP2020. ' (Site from Safety).	Danuel Hamlin (b) (4)	05 Nov 2020 20:14:20

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT IS 43 YEAR OLD WOMAN WITH SOCIAL RISK FOR COVID-19. SHE CONSENTED AND RANDOMIZED ON 11AUG2020 AND TOLERATED DOSE 1 UNEVENTFULLY. SHE DEVELOPED NEW ONSET INCREASED DYSPNEA AND FLUID RETENTION THAT BECAME CLINICALLY BOTHERSOME ON 08:00 ON 03SEP2020. SHE WENT TO ROGUE REGIONAL MEDICAL CENTER IN MEDFORD, OR AT APPROXIMATELY 09:00 ON 04SEP2020, AND WAS ADMITTED FOR NEW ONSET CONGESTIVE HEART FAILURE (CHF). CHF WAS CONFIRMED ON CHEST X-RAY AND ECHOCARDIOGRAM, AND OTHER HEART DISEASE WAS RULED WITH ANGIOGRAM AND CHEST CT. PATIENT WAS DIURESED WITH FUROSEMIDE AND RECOVERED FULLY. SHE WAS DISCHARGED TO HOME ON 09SEP2020 AT ABOUT 17:00 ON NEW ORAL DIURETIC MEDICATIONS TO PREVENT CHF. ALL HISTORY FROM PHONE CALL TO PATIENT ON 09SEP2020 AT 18:30. WE ARE REPORTING THIS SAE TODAY. SAE report updated 05NOV2020 based on hospital discharge summary. DC summary confirms admit date was 05SEP2020 and DC date 09SEP2020. Primary diagnosis was acute CHF that improved after 2 liters diuresis with furosemide. Echo confirmed low LVEF of 30% confirming systolic CHF. Subject also had a left heart catheterisation test performed which showed normal coronary arteries. Family history was positive for (b) (6) and (b) (6). (b) (6) both dying in 40s with possible familial cardiomyopathy and CHF. Subject also had remote history of methamphetamine abuse 1993-2003 that may have contributed to cardiomyopathy. Therefore, patient seems to have a previously undiagnosed familial cardiomyopathy which may be do to A) history of CHF in (b) (6) and (b) (6), B) weight lifting and methamphetamine abuse as teenager and young	Danuel Hamlin (b) (4)	05 Nov 2020 20:13:49

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Narrative](#)

Audit	User	Time (GMT)
adult, and C) patient also seems to have borderline diabetes type II that may contribute to cardiomyopathy. She was discharged to home on new meds for cardiomyopathy including 5 medications, and with follow-up with cardiologist planned in 2-3 months. SAE is updated today with this information from hospital records.' reason for change: New Information		
Query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' answered with 'Added' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 15:38:09
User opened query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:34:05
User opened query 'PV Query: Please provide echocardiogram results.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 13:43:46
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 13:43:34

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient is 43 year old woman with social risk for COVID-19. She consented and randomized on 11AUG2020 and tolerated Dose 1 uneventfully. She developed new onset increased dyspnea and fluid retention that became clinically bothersome on 08:00 on 03SEP2020. She went to Rogue Regional Medical Center in Medford, OR at approximately 09:00 on 04SEP2020, and was admitted for new onset congestive heart failure (CHF). CHF was confirmed on Chest X-ray and echocardiogram, and other heart disease was ruled with angiogram and chest CT. Patient was diuresed with furosemide and recovered fully. She was discharged to home on 09SEP2020 at about 17:00 on new oral diuretic medications to prevent CHF. All history from phone call to patient on 09SEP2020 at 18:30. We are reporting this SAE today.'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiomyopathy, LLT: Cardiomyopathy - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 23:16:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	05 Nov 2020 23:16:33
Data point term sent to Coder	System	05 Nov 2020 20:17:55
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '05 Sep 2020'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Query 'Per CDM: Per previous query, start time is not required for this AE as it did not occur within 24 hours of receiving Investigational Product. Please delete entry for start time.' answered with 'Deleted' (Site from DM).	Danuel Hamlin (b) (4)	25 Nov 2020 02:26:35
DataPoint Un-verified.	Danuel Hamlin (b) (4)	25 Nov 2020 02:26:27
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	25 Nov 2020 02:26:27
User opened query 'Per CDM: Per previous query, start time is not required for this AE as it did not occur within 24 hours of receiving Investigational Product. Please delete entry for start time.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 15:14:31
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 15:13:44
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Confirmed.' (Site from System).	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:35
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Nov 2020 20:17:25
User entered '12:00'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 02:26:27
User entered '05 Sep 2020 12:00'	System	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'Corrected' (Site from DM). DataPoint Un-verified.	Danuel Hamlin (b) (4) [REDACTED]	25 Nov 2020 02:27:13
	Danuel Hamlin (b) (4) [REDACTED]	25 Nov 2020 02:27:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danuel Hamlin (b) (4) [REDACTED]	25 Nov 2020 02:27:08
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	18 Nov 2020 10:17:06
	(b) (4), (b) (6) [REDACTED]	05 Nov 2020 23:20:26
User entered 'Not Applicable (NOT APPLICABLE)'	Danuel Hamlin (b) (4) [REDACTED]	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'None (NONE)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '1'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '1'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 20:17:25

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:31:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:17:25

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:31:07

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Query 'Re-query: Please reconcile as no new medications added. As noted multiple medications not in EDC but are in SAE medical records.' answered with 'Added' (Site from CRA).	Danuel Hamlin (b) (4)	25 Nov 2020 02:27:28
User opened query 'Re-query: Please reconcile as no new medications added. As noted multiple medications not in EDC but are in SAE medical records.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:58:39
User closed query 'Multiple CON-meds such as Hydrocodone not listed. Please refer to SAE medical records. Thanks ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:58:39
Query 'Multiple CON-meds such as Hydrocodone not listed. Please refer to SAE medical records. Thanks ' answered with 'Medications have been added' (Site from CRA).	Danuel Hamlin (b) (4)	09 Nov 2020 08:41:32
User opened query 'Multiple CON-meds such as Hydrocodone not listed. Please refer to SAE medical records. Thanks ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 23:18:29
User closed query 'Per ETRTR: Ensure updating ConMeds provided for SAE "Congestive heart failure", thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 23:18:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:11:37
Query 'Per ETRTR: Ensure updating ConMeds provided for SAE "Congestive heart failure", thanks.' answered with 'Added' (Site from CRA).	Danuel Hamlin (b) (4)	04 Nov 2020 15:44:37
User opened query 'Per ETRTR: Ensure updating ConMeds provided for SAE "Congestive heart failure", thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Sep 2020 19:02:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:06:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:08:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:08:17
Data point term sent to Coder	System	13 Aug 2020 02:07:19
User entered 'Synthroid'	(b) (4), (b) (6) (b) (4)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:35:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Hypothyroidism'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '112'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:10:19
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 19:56:28
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Oct 2020 19:56:16
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:12:06
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User closed 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).	(b) (4), (b) (6)	14 Aug 2020 23:51:01
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.'	(b) (4), (b) (6)	13 Aug 2020 02:07:07
answered with 'confirmed' (Site from System).		
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	13 Aug 2020 02:06:56
User entered 'un UNK 2005'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE HYDROCHLORIDE, PRODUCTSYNONYM: REQUIP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:09:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:09:19
Data point term sent to Coder	System	13 Aug 2020 02:08:22
User entered 'Requip'	(b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:35:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Restless Leg Syndrome'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '2.5'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User closed 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).	(b) (4), (b) (6)	14 Aug 2020 23:51:07
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.'	(b) (4), (b) (6)	13 Aug 2020 02:08:14
answered with 'confirmed' (Site from System).		
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	13 Aug 2020 02:08:03
User entered 'un UNK 2007'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:10:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:10:20
Data point term sent to Coder	System	13 Aug 2020 02:09:23
User entered 'Ibuprofen'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:35:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Occasional Headache'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '800'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User closed 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).	(b) (4), (b) (6)	14 Aug 2020 23:51:11
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.'	(b) (4), (b) (6)	13 Aug 2020 02:09:07
answered with 'confirmed' (Site from System).		
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	13 Aug 2020 02:08:54
User entered 'un UNK 2000'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:51:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:51:33
Data point term sent to Coder	System	05 Nov 2020 20:35:52
User entered 'Aspirin'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Cardiac Prophylaxis'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '81'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '09 Sep 2020'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:15:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:15:23
Data point term sent to Coder	System	05 Nov 2020 20:37:56
User entered 'Atorvastatin'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '40'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '08 Sep 2020'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:34:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:34:29
Data point term sent to Coder	System	05 Nov 2020 20:38:59
User entered 'Carvedilol'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '3.125'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'twice daily (BID)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '09 Sep 2020'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:36:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:36:31
Data point term sent to Coder	System	05 Nov 2020 20:38:59
User entered 'Furosemide'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '20'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '10 Sep 2020'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:11:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:11:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
Data point term sent to Coder	System	05 Nov 2020 20:40:08
User entered 'Lisinopril'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '2.5'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '10 Sep 2020'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:42:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:42:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
Data point term sent to Coder	System	05 Nov 2020 20:40:10
User entered 'Spironolactone'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '6.25'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '10 Sep 2020'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:44:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:44:24
Data point term sent to Coder	System	05 Nov 2020 20:43:14
User entered 'Lantus'	Danuel Hamlin (b) (4) (b) (4) (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Type II Diabetes'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '22'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Other (OTHER)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'units'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'un UNK 2019'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:14:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:14:30
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
Data point term sent to Coder	System	05 Nov 2020 20:44:18
User entered 'Insulin Lispro'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Type II Diabetes'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '2'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Other (OTHER)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Units'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'as needed (PRN)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'un UNK 2019'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 20:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 20:44:08
User entered 'No (N)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:08
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 20:44:03
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:27:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:27:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
Data point term sent to Coder	System	05 Nov 2020 20:48:44
User entered 'Albuterol'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Exertional Bronchospasm'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '180'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'ug (ug)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'as needed (PRN)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'un UNK 2018'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:31:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:38:52

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:31:07

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020'	Danuel Hamlin (b) (4)	04 Nov 2020 15:39:22

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:31:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Echocardiogram'	Daniel Hamlin (b) (4)	04 Nov 2020 15:39:22

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:39:22

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:31:07

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	04 Nov 2020 15:39:22

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:31:07

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020'	Danuel Hamlin (b) (4)	04 Nov 2020 15:40:09

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:31:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CAT Scan'	Danuel Hamlin (b) (4)	04 Nov 2020 15:40:09

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:40:09

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:31:07

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	04 Nov 2020 15:40:09

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:31:07

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Danuel Hamlin (b) (4)	04 Nov 2020 15:40:40

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:31:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Chest X-ray'	Danuel Hamlin (b) (4)	04 Nov 2020 15:40:40

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:40:40

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:31:07

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	04 Nov 2020 15:40:40

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:31:07

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Danuel Hamlin (b) (4)	04 Nov 2020 15:41:10

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:31:07

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Angiogram'	Danuel Hamlin (b) (4)	04 Nov 2020 15:41:10

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:31:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Danuel Hamlin (b) (4)	04 Nov 2020 15:41:10

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:31:07

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Danuel Hamlin (b) (4)	04 Nov 2020 15:41:10

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'USA-US093-2020-MRNA-1273-P301000003'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:48:58

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:48:58

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:32:40
User entered 'US' (non-conformant).	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 18:49:00
User entered '1'	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'USA-US093-2020-MRNA-1273-P301000003'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:48:58

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:48:58

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:32:40
User entered 'US' (non-conformant).	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 18:49:00
User entered '1'	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
User entered '12/Sep/2020 11:31'	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:07

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 22:47:54
User entered '1'	(b) (4), (b) (6)	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'USA-US093-2020-MRNA-1273-P301000003'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:48:58

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:48:58

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:47:54
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:32:40
User entered 'US' (non-conformant).	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 18:49:00
User entered '1'	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '06/Nov/2020 13:48'	System	06 Nov 2020 18:49:00

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 18:49:00